

PACKAGE INSERT

Encore A

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

**Encore A (METHAFILCON A) AND OMEGA 56 (ETAFILCON A)
DAILY WEAR SOFT CONTACT LENS**

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

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DESCRIPTION:

The **Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** are available as a single vision lens.

The lens material of **Encore A (Methafilcon A)** is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid cross-linked with ethyleneglycol dimethacrylate (45.0%) and water (55.0%).

The **OMEGA 56 (Etafilcon A)** is a co-polymer of HEMA and methacrylic acid cross-linked with trimethylolpropane trimethacrylate and ethylene glycol dimethacrylate and 58% water. It consists of UV Blocker; a Benzophenone UV absorbing monomer that used to block UV radiation. The UV blocking for averages > 99% in the UVB range of 280nm - 315nm and 83% in the UVA range of 316 - 380nm.

The **Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** are available with a blue visibility-handling tint, color additive: Reactive Blue 19.

The **Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** are hemispherical flexible shell which cover the cornea and portion of the adjacent sclera with the following dimensions:

Chord Diameter	:	14.0mm to 15.0mm
Center Thickness	:	0.06mm to 0.40mm
Base Curve (Encore A)	:	8.40mm to 9.30mm
Base Curve (OMEGA 56)	:	8.00mm to 9.80mm
Powers	:	-20.00 Diopters to +20.00 Diopters

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.

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The physical/optical properties of the **Encore A (Methafilcon A)** are:

Refractive Index (wet)	:	1.42
Light Transmittance	:	Approximately 98%
Surface Character	:	Hydrophilic
Water Content	:	55%
Oxygen Permeability (Dk)*	:	18.8 x 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mmHg) @ 35°C

The physical/optical properties of the **OMEGA 56 (Etafilcon A)** are:

Refractive Index (wet)	:	1.4050
Light Transmittance	:	greater than 91%
Surface Character	:	Hydrophilic
Water Content	:	58 %
Oxygen Permeability (Dk)*	:	21.83 x 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mmHg) @ 35°C

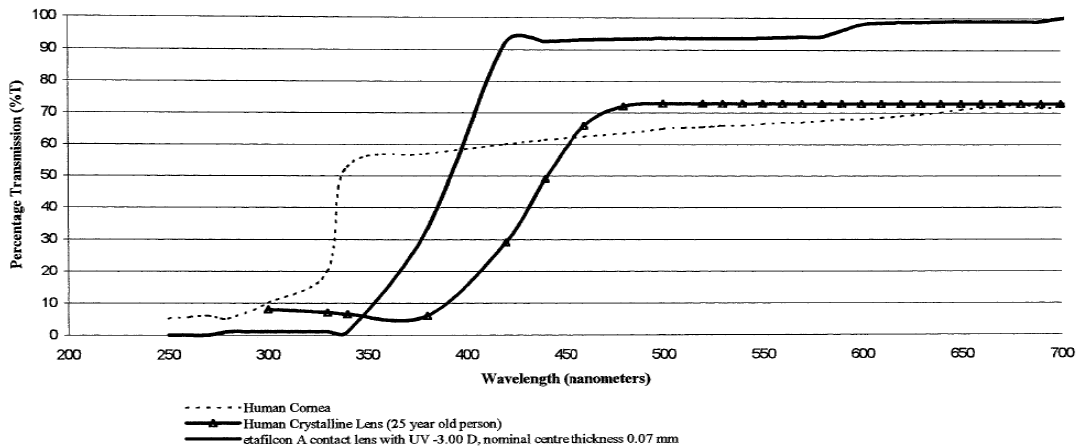
*[Fatt Method for determination of oxygen permeability]

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 **OMEGA 56 (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.

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



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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 their hydrated state, the **Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** when placed on the cornea act as refracting media (except for plano lenses) to focus light rays on the retina. The near portion of the aspherical design places the incoming light rays on the retina when viewing reading material at the reading distance.

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.

INDICATIONS:

The **Encore A (Methafilcon A) Soft (hydrophilic) Contact Lens** is indicated for daily wear for the correction (except for plano lenses) of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The **OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** is indicated for daily wear for the correction of visual acuity (except for plano lenses) in aphakic and not aphakic persons with non-diseased eyes with myopia and 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.

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The lenses may be cleaned and disinfected using a chemical or hydrogen peroxide disinfection system. Eyecare practitioners may prescribe the lenses for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfection systems.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the **Encore A (Methafilcon A) or OMEGA 56 (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.
- 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.

WARNINGS:

Patients should be advised of the following warnings pertaining to contact lens wear:

- PROBLEMS WITH THE CONTACT LENSES 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 lenses and lens care products, including the lens case. EYE PROBLEMS, INCLUDING CORNEAL ULCERS CAN DEVELOP RAPIDLY AND LEAD TO **LOSS OF VISION**.
- Daily wear lenses are not indicated for overnight wear and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than non smokers.
- IF A PATIENT EXPERIENCES EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, THE PATIENT SHOULD BE INSTRUCTED TO **IMMEDIATELY REMOVE THE LENSES** AND PROMPTLY CONTACT HIS OR HER EYECARE PRACTITIONER.

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PRECAUTIONS:

- 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 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.

- Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Aphakic patients should not be fitted with **Encore A (Methafilcon A) or OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** until the determination is made that the eye has healed completely.
- Fluorescein, a yellow dye, should not be used while the lens is on the eye. The lenses absorb this dye and become discolored. Whenever fluorescein is used in the eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use; and the patient should wait at least 1 hour before replacing the lenses.
- Before leaving the eyecare practitioner office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.

Eyecare practitioners 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 lenses. Use only recommended solutions.
- Never use solutions recommended for conventional hard contact lenses only.
- 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 solutions for lubricating or rewetting lenses.

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- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying may damage the lenses. Follow the lens care directions for CARE FOR A DRIED OUT (DEHYDRATED) LENS if lens surface does become dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on CARE FOR A STICKING (NON-MOVING) 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 lenses. Do not get cosmetics, lotions, soaps, creams, deodorant, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur causing distorted vision and/ or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instruction/ Wearer's Guide for the **Encore A and OMEGA 56 Soft (hydrophilic) Contact Lens** and those prescribed by the eyecare practitioner.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can discolor the lenses.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eyecare practitioner about wearing lenses during sports activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses 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 lenses.
- 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.
- The **Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** when prescribed in a Frequent Replacement Program are intended to be disposed of at the end of the prescribed period (1 week, 2 weeks, or 1 month). Therefore, it is important to always have available a pair of replacement lenses.

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ADVERSE REACTIONS:

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

- Eye pain, sting, burn, itch (irritation)
- Comfort is less than when lens was first placed on eye
- Abnormal feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Dry and redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)

If the patient notices any of the above, he or she should be instructed to:

- **IMMEDIATELY REMOVE LENSES.**
- If the discomfort or problem stops, then look closely at the lens.
- If the lens is in any way damaged, **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 lenses; then reinsert them.
- After reinsertion, if the problem continues, the patient should **IMMEDIATELY REMOVE THE LENSES AND CONSULT THE EYECARE PRACTITIONER.**

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 lenses apply to the **Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens**. For a detailed description of the fitting techniques, refer to the **Encore A and OMEGA 56 Soft (hydrophilic) Contact Lens Professional Fitting Guide and Patient Instruction/ Wearer's Guide**, copies of which 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

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WEARING SCHEDULE:

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER. Patients tend to overwear the lenses 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 **Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** are indicated for daily wear. The maximum suggested wearing time for the lenses is:

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

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens IS SAFE TO WEAR DURING SLEEP.

- WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER.

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: First Clean and Rinse, Then Disinfect Lenses

Basic Instructions

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use **FRESH, UNEXPIRED LENS CARE SOLUTIONS**. Never re-use the solution.
- Use the recommended system of lens care, either chemical (not heat), or oxidation (hydrogen peroxide) and carefully follow the 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 lenses. Do not put lenses into 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. **Disinfecting** is necessary to destroy harmful germs.

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- Always remove, **clean, rinse and disinfect** lenses according to the schedule prescribed by the eyecare practitioner. The use of enzyme or any cleaning solution does not substitute for disinfecting.
- The eyecare practitioner should recommend a care system is appropriate for the **Encore A (Methafilcon A) or OMEGA 56 (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.

Chemical Disinfecting Method

- **Clean** one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline 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 lenses, disinfect and leave them in the closed/ unopened case until ready to wear. Lenses stored longer than 12 hours may require cleaning, rinsing and disinfecting again before use. The patient should consult the package insert or the eye care practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the 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 fresh disinfecting/ storage solution. Replace lens case at regular intervals.
- **DO NOT HEAT THE DISINFECTING SOLUTION AND LENSES.**

Hydrogen Peroxide Disinfecting Method

- **Clean** one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or neutralizing 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.
- When using hydrogen peroxide lens care system, lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with fresh saline or neutralizing solution before inserting and wearing, or follow the instructions on the hydrogen peroxide system labeling.
- **DO NOT HEAT THE HYDROGEN PEROXIDE SOLUTION AND LENSES.**
- Leave the lenses in the unopened storage case until ready to put on the eyes.

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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 saline solution prior to placement on the eye should reduce the potential for irritation.

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 lenses and eyes. If these deposits are not removed, they can damage the lenses 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.

Lens Case Cleaning and Maintenance:

Contact lens cases can be a source of bacteria growth. Lens case should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eyecare practitioner.

Care for a Dried Put (Dehydrated) Dry Lens:

If the **Encore A (Methafilcon A)** or **OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** are off the eye and exposed to air for twenty minutes or longer, they will become dry and brittle. To rewet lenses:

- Place the lens in its storage case and soak the lens in recommended rinsing and storage solution for at least one hour or until the lens again feels soft and pliable.
- Clean, rinse and disinfect the rewetted lens using the lens care system recommended by the eye care practitioner.
- If after soaking, the lens does not become soft or the surface remains dry, **DO NOT PLACE THE LENS IN THE EYE**. Contact the eye care practitioner.

Care for a Sticking Lens:

If the lens sticks (cannot be removed), the patient should be instructed to apply 1 to 2 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 5 minutes, the patient should **IMMEDIATELY** consult the eyecare practitioner.

In Office Care Regimen For Trial Lenses:

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

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Each contact lens is shipped sterile in a blister pack with sterile saline solution. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the blister pack should not be opened until immediately prior to use. Lenses should be surface cleaned and disinfected prior to re-using in a diagnostic procedure or before dispensing to a patient.

Follow the disinfection procedure described above for proper disinfection of office trial lenses.

Frequent Replacement Program:

For complete information concerning the Frequent Replacement Program, please refer to the Professional Fitting Guide for the **Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens.**

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.

HOW SUPPLIED:

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

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the **Encore A (Methafilcon A) or OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** should be reported to:

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

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CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner.

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