

PACKAGE INSERT

For the **IntelliWave³KeraSoft[®] IC (Efofilcon A) SOFT (hydrophilic) SILICONE HYDROGEL CONTACT LENS FOR DAILY WEAR**

CAUTION: FEDERAL (USA) 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 wearer's guide that pertains to the patients prescribed lens.

DESCRIPTION

The **IntelliWave³KeraSoft IC** Silicone Hydrogel Soft Contact Lenses are fabricated from efofilcon A, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The non-ionic lens material, (efofilcon A) is a group 2, daily wear silicone hydrogel contact lens that is not surface treated and characterized by a high water content. The lens material is composed of silicone monomers cross linked with other monomers, and optionally incorporates D&C Green 6 as an integrated handling tint. The lenses are made by lathe-cut for custom Rx. It consists of 26% efofilcon A and 74% water by weight when immersed in a buffered saline solution. The (efofilcon A) name has been adopted by the United States Adopted Names Council (USAN).

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 (efofilcon A) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The Physical properties of the lens are:

Refractive Index	1.38
Light Transmission	greater than 97%
Surface Character	hydrophilic
Water Content	74 %
Specific Gravity	1.048 (hydrated)
Oxygen Permeability	59.8×10^{-11}
(cm ² /sec) (ml O ₂ /ml x hPa @ 35 °C), (revised Fatt method).	

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 74% water by weight. The lenses will be manufactured in spherical, aspherical, toric, multifocal, multifocal toric and irregular Cornea configurations with the following features and properties.

Chord Diameter	12.0 mm to 16.00 mm
Center Thickness	0.01 mm to 0.50 mm
Base Curve	7.00 mm to 9.5 mm
Cylinder Power (Toric)	-0.25D to -12.00D
Cylinder Power (Multifocal Toric)	-0.25D to -12.00D
Add Power (Multifocal)	+0.50D to +4.00D

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 **IntelliWave³KeraSoft IC Silicone Hydrogel Daily Wear Soft Contact Lens** has a spherical back 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.

ACTIONS

In its hydrated state, the **IntelliWave³KeraSoft IC (efofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens**, when placed on the cornea, act as a refracting medium to focus light rays on the retina.

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

- o The **IntelliWave³sphere** (efofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.
- o The **IntelliWave³toric** (efofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 12 diopters.
- o The **IntelliWave³multifocal** (efofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding .75 diopters and are presbyopic requiring add power of up to +4.00 diopters.
- o The **IntelliWave³multifocal toric** (efofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters.
- o The **/KeraSoft IC**, irregular cornea (efofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons and may be prescribed in otherwise non-diseased eyes that require a Soft Contact Lens for the management of irregular corneal conditions such as keratoconus and post graft fitting.

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 **IntelliWave³KeraSoft IC Silicone Hydrogel Daily Wear Soft Contact Lens** 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, other than conditions such as keratoconus, pellucid marginal degeneration, or post-refractive (e.g., LASIK) surgery, 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 **IntelliWave³KeraSoft IC Silicone Hydrogel Daily Wear Soft Contact Lens**.
- 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.

WARNINGS

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN CORNEAL INFECTION AND/OR ULCER AND LEAD TO LOSS OF VISION. It is essential that the patient follows their eyecare practitioner's direction and all labeling instructions for proper use of lenses and lens care products, including the lens case.

- o The patient should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect their lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean the lenses.
- o The patient should fill their lens case with fresh solution every time they store their lenses, and never "top-off" or re-use solution. The patient should discard their solution immediately after the lenses have been removed from the lens case. The patient should not expose or store their lenses in or rinse their lens case with any water, such as tap, bottled or distilled, or with any non-sterile solution.
- o The patient should clean, rinse and air-dry their lens case each time they remove their lenses. In order to permit excess solution to drain, they can flip over the lens case while air drying. Replace the lens case frequently, depending upon the patient's hygiene habits.
- All contact lens wearers must see their eyecare practitioner as directed.
- Daily wear lens are not indicated for overnight wear, and patients should be instructed not to wear lens while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when this lens is 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

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 were 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
- Fluorescein, a yellow dye, should not be used while the lens is on the eye. The lens will absorb this dye and become discolored. Whenever Fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in eye use. Wait at least one hour before replacing the lens. Too early replacement may allow the lens to absorb residual Fluorescein irreversibly.
- Before leaving the eyecare practitioner's office, the patient should be able to promptly remove lens or should have someone else available who can remove the lens for him or her.
- Eyecare practitioners should instruct the patient to remove the lens immediately if the eye becomes red or irritated.

Eyecare practitioners should carefully instruct patients about the following 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 that are fresh and sterile. Never use solutions recommended for conventional hard contact lens only. Chemical disinfection solutions should not be used with heat. Always use **FRESH, STERILE UNEXPIRED** lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions. Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions. Do not use saliva or anything other than the recommended solution for lubricating or rewetting lens. Always keep the lens completely immersed in the recommended storage solution when the lens is not being worn (stored). Prolonged periods of drying will damage the lens. Follow the lens care directions for (Care for a Dried Out Dehydrated Dry Lens) if the lens surface does become dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on (care for sticking non-moving lens). The lens should move freely on the eye for the continued health of the eye. If 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 microscope scratches of the lens may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and wearing instructions in the patient instructions for the **IntelliWave³KeraSoft IC Silicone Hydrogel Daily Wear 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 discard lenses worn on a frequent replacement schedule after the recommended wearing schedule prescribed by the eyecare practitioner.
- Always contact the eyecare practitioner before using any medicine or medications in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lens.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

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.
- During use for the management of irregular corneal conditions, an adverse effect may be due to the original condition or may be due to the effects of wearing a contact lens. There is a possibility that the existing condition might become worse when a lens is used on an eye with an irregular corneal condition. The patient should be instructed to avoid serious eye damage by contacting the eyecare professional IMMEDIATELY if there is an increase in symptoms while wearing the lens.

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

- **IMMEDIATELY REMOVE LENS.**
- If discomfort or problems stop, then look closely at the lens. If the lens is in anyway 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 LENS 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 lens do and do not apply to the **IntelliWave³/KeraSoft IC Silicone Hydrogel Daily Wear Soft Contact Lens**. For a detailed description of the fitting techniques, refer **IntelliWave³/KeraSoft IC Silicone Hydrogel Daily Wear Soft Contact Lens** Professional Fitting and Information Guide, copies of which are available from:

Art Optical Contact Lens, Inc., 3175 3 Mile Road NW, Walker, Michigan 49534 **Toll Free Number: 800-253-9364 Online: www.artoptical.com**

WEARING SCHEDULE

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER. Patients tend to over wear the lens initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

For the management of irregular corneal conditions, close supervision by the eyecare professional is necessary. The eyecare professional should determine the appropriate wearing time and provide specific instructions to the patient regarding lens care, insertion and removal.

The **IntelliWave³, Silicone Hydrogel Daily Wear Soft Contact Lenses** are indicated for daily wear. The maximum suggested wearing time for this lens is:

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

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE IntelliWave³/KeraSoft IC Silicone Hydrogel Daily Wear 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 **IntelliWave³/KeraSoft IC Silicone Hydrogel Daily Wear Soft Contact Lens** be discarded and replaced with a new lens every three (3) months. 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 instructions on the lens care regimen recommended for the patient:

Basic Instructions:

Care of contact lens takes very little time and involves **THREE** essential steps – **CLEANING, RINSING AND DISINFECTING**. Each step in itself is important, and one step is not to be replaced by the other. Always wash, rinse and dry hands before handling contact lens. Always use **FRESH, STERILE UNEXPIRED** lens care solutions. Use the recommended chemical (not heat) lens care system. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING**. 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.

The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfection solution prior to disinfecting the lens. 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.

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 manufacture 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.

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 **IntelliWave³/KeraSoft IC Silicone Hydrogel Daily Wear Soft 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), 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 nonmovement of the lens continues after 15 minutes, the patient should **IMMEDIATELY** consult the eyecare practitioner.

Storage:

The **IntelliWave³/KeraSoft IC Silicone Hydrogel Daily Wear Soft 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:

It is recommended that the **IntelliWave³/KeraSoft IC Silicone Hydrogel Daily Wear Soft Contact Lens** be discarded and replaced with a new lens every three (3) months. However, as the Eyecare practitioner, you are encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

Chemical (NOT HEAT) Lens Disinfection:

Wash and rinse your hands thoroughly BEFORE HANDLING LENS.

- 1) Place lens in the palm of your hand.
- 2) Apply 1 or 2 drops of cleaner to each lens surface and gently rub with the forefinger of the opposite hand.
- 3) Clean for about 15 – 20 seconds
- 4) Rinse the lens thoroughly with sterile saline solution. DO NOT use water to rinse your lenses.
- 5) After rinsing, place the lens in a storage case.
- 6) Repeat the process with the other lens.
- 7) Disinfect lenses as per manufacturer's instructions.

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 daily 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 **IntelliWave³/KeraSoft IC Silicone Hydrogel Daily Wear Soft Contact Lens**. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed. The table below shows solutions that are recommended for use with the **IntelliWave³/KeraSoft IC Silicone Hydrogel Daily Wear Soft Contact Lens**.

Daily Cleaner:	<ul style="list-style-type: none">• Opti-Free Daily cleaner by Alcon
Rinsing Solution:	<ul style="list-style-type: none">• Opti-Free Pure Moist by Alcon
Disinfecting Solution:	<ul style="list-style-type: none">• Opti-Free Pure Moist by Alcon
Lubricant/Rewetting Drops:	<ul style="list-style-type: none">• Opti-Free Express by Alcon
Enzymatic/Protein Cleaner:	<ul style="list-style-type: none">• SupracLens by Alcon
Oxidation Systems	<ul style="list-style-type: none">• 3% H₂O₂ with neutralizing disc

EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should:

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

HOW SUPPLIED:

Each lens is supplied sterile in a sealed glass vial containing buffered normal saline solution. The glass vial is marked with the base curve, diameter, dioptric power, manufacturing lot number, and expiration date of the lens.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the **IntelliWave³/KeraSoft IC Silicone Hydrogel Daily Wear Soft Contact Lens** or experienced with the lens should be reported to:

Art Optical Contact Lens, Inc., 3175 3 Mile Road NW, Walker, Michigan 49534 **Toll Free Number: 800-253-9364** **www.artoptical.com**

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