PACKAGE INSERT

For the IntelliWave® KeratSoft® IC (Efroticon A) SOFT (hydrophilic) SILICONE HYDROGEL CONTACT LENSES FOR DAILY WEAR

IMPORTANT INFO
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 IntelliWave® KeratSoft® IC Soft Silicon Hydrogel Contact Lenses are fabricated from efroticon A, in which 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 IntelliWave® KeratSoft® IC lens, daily wear silicone hydrogel contact lens that is not surface treated and characterized by a high water content. The lens is 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 lot and are custom Rx. It consists of 26% efroticon A and 74% water by weight when immersed in a buffered saline solution. The (efroticon A) name has been adopted by the United States Adopted Names Council (USAN) Committee on Nomenclature. The IntelliWave® KeratSoft® IC 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.

Oxygen Permeability
Effort is made to incorporate the lens design and parameters so that 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.

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 Physical properties of the lens are:

- Refractive index: 1.38
- Light Transmission: greater than 97%
- Surface Permeability: hydrophilic
- Center Thickness: 34 %
- Specific Gravity: 1.048 (Hydrated)
- Oxygen Permeability: 59.8 x 10^-11 cm^3 (cm H2O)/m^2 atm (0.15% NaCl, 37°C, revised Fatt method).

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens

- Chord Diameter: 12.0 mm ± 0.00 mm
- Center Thickness: 0.01 mm ± 0.00 mm
- Base Curve: 7.00 mm ± 0.05 mm
- Cylinder Power (Toric): -0.25 to -12.00 D
- Cylinder Power (Multifocal): -0.25 to -12.00 D

The IntelliWave® KeratSoft® IC Silicone Hydrogel Contact Lenses for daily wear, when placed on the cornea, act as a refracting medium to focus light rays on the retina. The patient should be closely monitored by the prescribing eyecare practitioner.

Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers do.

Caution: Patients unable to follow the care regimen or unable to obtain assistance to do so.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN CORNEAL INFECTION AND/OR ULCER AND LEAD TO LOSS OF VISION. 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. Water-base cleaners may be prescribed as the lenses for frequent/preplanned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/preplanned 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 Contact Lens when any of the following conditions are present:

- Acute or subacute infection or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that may affect the eye or lens.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lens.
- Any active corneal infection (bacterial, fungi, or viral).
- Any allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for 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.
- Patients unable to follow the care regimen or unable to obtain assistance to do so.
- Patients who are aphagic contact lens wearers that may be at risk for the development of corneal ulceration.

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.

Patients unable to follow the care regimen or unable to obtain assistance to do so.

Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the IntelllWave® KeratSoft® IC Silicone Hydrogel Daily Wear Soft Contact Lens.

In the event of unanticipated problems, patients who are aphagic contact lens wearers may be at risk for the development of corneal ulceration.

IMMEDIATELY
Inform the doctor (health care practitioner) about being a contact lens wearer.

- Avoid all harmful or irritating vapors and fumes while wearing lens.
- Always wash and rinse hands before handling lens. Do not use saliva or anything other than the recommended solution for lubricating the lens case.
- Always follow directions in the package inserts for the use of contact lens solutions.  Always follow directions in the package inserts for the use of contact lens solutions.  Always follow directions in the package inserts for the use of contact lens solutions.  Always follow directions in the package inserts for the use of contact lens solutions.  Always follow directions in the package inserts for the use of contact lens solutions.

- Inform the doctor (health care practitioner) if the patient is diabetic or is taking medication that may affect the cornea.
- Inform the doctor (health care practitioner) about any systemic disease that may affect the eye or be exaggerated by wearing contact lens.
- Inform the doctor (health care practitioner) if the patient is unable to follow the lens care regimen or unable to obtain assistance to do so.
- Avoid 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 the lens case.

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- 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, STEERILIZED unpreserved lens care solutions.  Always follow directions in the package inserts for the use of contact lens solutions.  Always follow directions in the package inserts for the use of contact lens solutions.  Always follow directions in the package inserts for the use of contact lens solutions.  Always follow directions in the package inserts for the use of contact lens solutions.

- Do not touch contact lens with the fingers or hands if the hands are free of foreign materials, as microscopics of the hands may occur, causing decreased vision or injury to the eye.
- Do not touch the lenses with fingernails, dirt, debris, or other substances.
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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
- Failing that something is in the eye such as a foreign body or scratched area
- Excessive watering (tearing) of the eye
- Unusual eye secretions
- Rehension of the eye
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbow, or halo 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 is instructed to:
- IMMEDIATELY REMOVE LENS.
- If discomfort persists, see your eyecare practitioner.
- If discomfort 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

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. Patients tend to over wear 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.

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, if needed.

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

- 8 to 10 hours/day
- 14 hours/day

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.

One lens care product is not to be replaced by the other. Always wash, rinse and dry hands before handling contact lens. Always use FRESH, STERILE UNEXPLORED lens care solutions. Use the recommended chemical (not heat) lens care system. Different solutions cannot always be used for all lenses. Always use solutions that are safe for the lens and use all lenses. Do NOT ALTERATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING. Do not use saliva or anything other than the recommended solutions for lubricating or rehydrating lens. Do not put lens in the mouth. Lenses should be cleaned, rinsed, and disinfected each time they are removed. Cleaning and rinsing are necessary to remove mucoproteins and film from the lens surface. Disinfecting is necessary to destroy harmful germs. The lenses 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/wetting/solution, which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

Lens cleaning, disinfection, and storage:
- Clean lens: Once the patient takes the lens out of the case 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 proceed to 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, disinfected 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 lenses.

Lens Care Maintenance and Cleaning:
- Contact lens case 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 dry.

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 Lenses. Failure to follow this procedure may result in development of serious ocular infections.

For a care detail (dihydrated) 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.

Lens Care for a sticky (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 rehydrating solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If nonmovement of the lenses continues after 15 minutes, the patient should IMMEDIATELY contact the eyecare practitioner.

Cleaning and rinsing:
- Lens cleaning, disinfection, and storage:
- Disinfection:
- Lens Care Regimen:
- Lens Care Maintenance and Cleaning:
- Lens Care Cleaning and Maintenance:
- Lens Cleaning, Disinfection, and Storage:
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, dioptic 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 IntelliWave/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: 800-233-5064   www.artoptical.com

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