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**WARNINGS**

- DO NOT USE the cleaned and disinfected using a chemical (not heat) lens care system or hydrogen peroxide disinfection systems.
- 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.
- 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 medical devices sold under this label are intended for use by or on the order of a licensed practitioner.
- Pro/Kerasoft IC/Thin 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.

**WARNINGS**

- Any condition, such as myopia or thimerosal, in a solution which is to be used to care for the Pro/Kerasoft IC/Thin Silicone Hydrogel Daily Wear Soft Contact Lens.
- Any active corneal infection (bacterial, fungal, or viral).

**PRECAUTIONS**

- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers do.
- Selecting the most appropriate type of lens for each patient is critical.
- Patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when this lens is worn overnight.
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solution 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 the 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 disinfection. Cleaning and disinfection solutions should not be used with heat. Always use FRESH, STERILE UNEXPUNED lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions. Sterling 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 lenses. Always keep the lens completely immersed in the recommended storage solution when the lens is not being worn (stored).

- 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-motion 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, deodorants, or sprays in the eyes or on the lens. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses 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 IntelliWave Pro/Kerasoft IC/Thin Silicone Hydrogel Daily Wear Soft Contact Lens and those prescribed by the eyecare practitioner.

- Never wear lenses 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 lenses carefully and avoid dropping them.

- Avoid all harmful or irritating vapors and fumes while wearing lenses.

- Ask the eyecare practitioner about being a contact lens wearer.

- 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 a 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.

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.

- Blurred vision, rainbows, or halos around objects.

- Sensitivity to light (photophobia).

- Dry eyes.

- During use for the management of irregular cornal 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 cornal 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 reinset them.

- If after reinset, 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 IntelliWave Pro/Kerasoft IC/Thin Silicone Hydrogel Daily Wear Soft Contact Lens. For a detailed description of the fitting techniques, refer IntelliWave Pro/Kerasoft IC/Thin 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 cornal 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.

<table>
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<tr>
<th>The IntelliWave Pro/Kerasoft IC/Thin Silicone Hydrogel Daily Wear Soft Contact Lenses are indicated for daily wear. The maximum suggested wearing time for this lens is:</th>
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<td><strong>DAY</strong></td>
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FREQUENT/PLANNED REPLACEMENT

It is recommended that the IntelliWave Pro/Kerasoft IC/Thin Silicone Hydrogel Daily Wear Soft Contact Lens be discarded and replaced with a new lens every three (3) months. However, as the eyecare practitioner may determine to maintain and 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 UNEXPUNED 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 lenses. 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 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) 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:** 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.

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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 IntelliWave®/Intelliwave® Pro/Kerasoft IC/Thin Silicone Hydrogel Daily 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 lenses 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 IntelliWave®/Intelliwave® Pro/Kerasoft IC/Thin 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 lenses dehydrate, reference above section on caring for dried out (dehydrated) dry lenses.

Lenses prescribed for frequent replacement:
It is recommended that the IntelliWave®/Intelliwave® Pro/Kerasoft IC/Thin 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 lenses 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.

LENSES 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

| Daily Cleaner: | • Opti-Free Daily cleaner by Alcon |
| Rinsing Solution: | • Opti-Free Replenish by Alcon |
| Disinfecting Solution: | • Opti-Free Replenish by Alcon |
| Lubricant/Rewetting Drops: | • Opti-Free Express by Alcon |
| Enzymatic/Protein Cleaner: | • Opti-Free Superclean [MS1] by Alcon |
| Oxidation Systems: | • 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 IntelliWave®/Intelliwave® Pro/Kerasoft IC/Thin 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

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