WARNINGS

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

• If eyes become red or irritated.

• Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the lens.

• Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.

• Any systemic disease that may affect the eye or be exaggerated by wearing contact lens.

• Acute and subacute inflammation or infection of the anterior chamber of the eye.

OF THE EYE,

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 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.

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

CONTACT LENSES ARE NOT SAFE FOR USE IN ANY OF THE FOLLOWING CONDITIONS.

CAUTION

IntelliWave1/ Intelliwave1 Pro, Soft Daily Wear Contact Lens (Acofilcon B) Contact Lens when any of the following conditions are present:

- Acute eye infection or inflammation of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the conjunctiva, cornea, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eye).
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lens.
- Any 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 lens.
- Any active corneal infection (bacterial, fungal, or virus).
- If eyes become red or irritated.

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

PROBLEMS WITH CONTACT LENS AND LENS CARE PRODUCTS CAN RESULT IN SERIOUS INJURY TO THE EYE. It is essential for patients to follow their eyecare practitioner's directions and all labeling instructions for proper use of lens and lens care products, including the lens case. EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION. THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENS AND PROMPTLY CONTACT YOUR EYECARE PRACTITIONER.

All contact lens wearers must see their eyecare practitioner as directed.

Daily wear lenses 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 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 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.

Contact lens wearers who smoke have an increased risk of adverse reactions than nonsmokers do.

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If eyes become red or irritated.

Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the lens.

Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.

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

HOW SUPPLIED: DELAY.

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

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

- The eyecare practitioner should recommend a care system that is appropriate for the patient.
- 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 IntelliWave®/Intelliwave® Pro, Soft Daily Wear Contact Lens.

**RECOMMENDED LENS CARE PRODUCTS**

Enzymatic cleaning may be recommended by the eyecare practitioner. Enzymatic cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important to the health of the patient's lens and eyes. If these deposits are not removed, they can damage the lens and cause irritation. Enzymatic 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 CARES**

The eyecare practitioner should recommend a care system that is appropriate for the IntelliWave®/Intelliwave® Pro, Soft Daily Wear 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 IntelliWave®/Intelliwave® Pro, Soft Daily Wear Contact Lens.

**WEARING SCHEDULE**

**FREQUENT/PLANNED REPLACEMENT**

Art Optical recommends that the IntelliWave®/Intelliwave® Pro, Soft Daily Wear Contact Lens be discarded and replaced with a new lens every six 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**

**FEMALE**

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.
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.

**MEN**

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.
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.

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 storage 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.

Lens deposits are necessary to remove mucus and film from the lens surface. After removing the lens from the eye, completely 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 use. If not to be used immediately following disinfection, the previous night’s disinfecting solution may be used to consult the package insert or the eyecare practitioner for information on storage of lenses...

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.

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 washed, disinfected, and stored as directed 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 previous night’s disinfecting solution may be used to consult the package insert or the eyecare practitioner for information on storage of lenses...

Clean for about 15 – 20 seconds. Rinse the lens thoroughly with sterile saline solution. Do not use water to rinse your lenses. After rinsing, place the lens in a storage case. Repeat the process with the other lens.

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Conventional methods of fitting contact lenses do and do not apply to the IntelliWave®/Intelliwave® Pro, Soft Daily Wear Contact Lens. The maximum suggested wearing time for this lens is:

**WEARING SCHEDULE**

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MEMBERSHIPS AND USE OF ENZYMATIC CLEANER

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**RECOMMENDED LENS CARE CARES**

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