Following directions for routine lens care, including cleaning of the lens case. The lenses may be worn by persons who exhibit astigmatism in aphotic and non-aphotic persons with non-diseased eyes. They may be worn by persons who have astigmatism of 1.20 diopters or less. If Hydrasoft Toric lenses are indicated for daily wear, extended wear from 1 to 7 days before removal for cleaning and disinfecting as recommended by the eye care practitioner. They are indicated for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphotic and non-aphotic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism in 1.50 diopters or less that does not interfere with visual acuity. 3. Hydrasoft Toric lenses are indicated for daily wear for adults, correction of ametropia (myopia, hyperopia, and astigmatism) in aphotic and non-aphotic persons with non-diseased eyes. They may be worn by persons who have astigmatism of 1.20 diopters or less. 4. Hydrasoft Toric lenses are indicated for daily wear and extended wear from 1 to 7 days before removal for cleaning and disinfecting as recommended by the eye care practitioner. The correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphotic and non-aphotic persons with non-diseased eyes. The lenses may be worn by persons who have astigmatism in 1.50 diopters or less.

Note: Only chemical disinfection may be used with Hydrasoft lenses. With the Hydrasoft Options program, eye care practitioners may prescribe the lens for frequent replacement wear, with cleaning, disinfection, and scheduled replacement (see Warnings). CONTRAINDICATIONS (REASONS NOT TO USE): Do not use any Hydrasoft contact lens referred to in this package insert when any of the following conditions are present: Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids. Severe insufficiency of lacrimal secretion (dry eyes). Corneal hypoplasia (reduced corneal sensitivity), if not aphatic. Any systemic disease that may affect the eye or be exacerbated by wearing or inserting contact lenses. Allergic reactions of ocular surfaces or adnexa that may be induced or exacerbated 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 Hydrasoft lens. Refractive surgical infection (bacterial, fungal, or viral). If eyes become red or irritated. The patient is unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS: Problems should be advised of the following warnings pertaining to contact lens care: Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eye care practitioner’s directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems such as infections, corneal ulcers, can develop rapidly and lead to loss of vision.

All contact lens wearers must see their eye care practitioner as directed. If the lenses are for extended wear, the eye care practitioner may prescribe more frequent visits. Daily wear lenses are not indicated for overnight wear, and patients should not wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight. The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among users of daily wear lenses. The risk among extended wear users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens case. Studies have been shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers. If the patient experiences eye discomfort, excessive teardrop loss, change in vision, or any other abnormal condition should be instructed to immediately contact his or her eye care practitioner.

PRECAUTIONS: Special Precautions for Eye Care Practitioners Due to the small numbers of patients enrolled in clinical investigations of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, water content, central and peripheral thickness, and optic zone diameter. The potential impact of these factors on the patient’s ocular health should be carefully weighed against the patient’s needs for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

Visual acuity with high cylinder lenses will be equal to, or less than visual acuity with spectacles. The extended wear toric lens may provide visual acuity that is less than the stable daily toric wear. Aphakic patients should not be fitted with any Hydrasoft contact lens until the determination is made that the eyes has completely healed. Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb the dye and become yellow and opaque. Discarded lens solution, if used in the eyes, the lenses should be flushed with a sterile saline solution that is recommended for in-eye use. Before leaving the eye care practitioner’s office, the patient should be instructed that the lenses should be handled by someone else available who can remove the lenses for him or her. Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated. Aphagic patients should not be fitted with any Hydrasoft contact lens until the determination is made that the eyes has completely healed. Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb the dye and become yellow and opaque. Discarded lens solution, if used in the eyes, the lenses should be flushed with a sterile saline solution that is recommended for in-eye use. Before leaving the eye care practitioner’s office, the patient should be instructed that the lenses should be handled by someone else available who can remove the lenses for him or her. Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated. Eye care practitioners should carefully instruct patients about the following conditions and patient care 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 lenses only. Use only chemical (not heat) disinfection with Hydrasoft lenses. Heat disinfection should NOT be used. Repeated use of disinfection will cause irreversible damage to Hydrasoft lenses. Always use fresh, unexpired lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions. Sterile unsupervised 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 wetting lenses. 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 the lens surface does become dried out. If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movemement of the lenses continues, the patient should be instructed to immediately consult his or her eye care practitioner.

Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, detergents, or other oils on the lens or lens case. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based cosmetics.

Do not touch the contact lenses with the finger or hands if the hands are not free of foreign materials, as this may damage the lenses. Caring for the lens, handling, insertion, removal, cleaning, disinfecting, storing, and wearing instructions in the Patient Instructions for Hydrasoft contact lenses and those prescribed by the eye care practitioner.

Never wear lenses beyond the period recommended by the eye care practitioner. If aerosol products such as hairspray 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 handling or wearing lenses.

Ask the eye care practitioner about wearing the lenses during sporting 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 in the lens care directions.

Do not touch the lenses with fingerprints.

Always contact the eye care practitioner before using any medication that is absorbed through the conjunctiva.

Always remove 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.

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

Eye burning, itching, or rubbing irritation, or other eye pain. Comfort is less than when the lens was first placed on the eye. Feeling that something is in the eye such as a foreign body or a scratched area. Excessive watering (tearing) of the eyes. Unusual eye secretions. Redness of the eyes. Reduced sharpness of vision (poor visual acuity). Blurred vision, rainbows, or halos around objects. Sensitivity to light (photophobia). Dry eyes. If the patient notices any of the above, he or she should be instructed to:

Immediately remove the lenses.

If the discomfort or other problem stops, then look closely at the lens. If the lens is in some way damaged, do not put the lens back on the eye. Place the lenses in the care case and contact the eye care 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 both lenses; then reinsert them.

• After reinsertion, if the problem continues, the patient should immediately remove the lenses and consult the eye care practitioner.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iris may be present.

The patient should be instructed to keep the lenses 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 Hydrasoft contact lenses. For a detailed description of the fitting techniques, refer to the Hydrasoft Professional Fitting and Information Guide, copies of which are available from:

WEARING SCHEDULE: The wearing and replacement schedules are determined by the eye care practitioner. Patients tend to overwear lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner are also extremely important.

With the Hydrosoft Options program, the lens may be discarded and replaced with a new lens on a frequent replacement basis. The eye care practitioner is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

DAILY WEAR: (less than 24 hours, while awake).

Hydrasoft and Hydrosoft Toric lenses are indicated for daily wear. The maximum suggested wearing time is:

<table>
<thead>
<tr>
<th>Day</th>
<th>Hours</th>
<th>Day</th>
<th>Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>2</td>
<td>10</td>
<td>14</td>
<td>10</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
<td>6</td>
<td>All waking hours</td>
</tr>
</tbody>
</table>

Studies have not been completed to show that Hydrasoft or Hydrosoft Toric lenses are safe to wear during sleep.

EXTENDED WEAR: (greater than 24 hours, including while asleep).

Hydrosoft Toric XIV and Hydrosoft Toric XIV lenses are suitable for extended wear. The wearing time should be determined by the eye care practitioner. First time wearers of contact lenses should begin by following the DAILY WEAR SCHEDULE above, as directed by the eye care practitioner.

CAUTION: Not every patient is able to wear Hydrosoft Toric XIV or Hydrosoft Toric lenses without some degree of irritation. Even if able to wear the lenses for daytime wear, the eye care practitioner will determine the best wearing schedule for each patient. The patient should start with daily wear of the lenses before extended wear so if directed by the eye care practitioner.

EXTENDED WEAR LENSES MUST BE REMOVED, CLEANED, AND DI SINFECTED AT LEAST ONCE EVERY 7 DAYS, as recommended by the eye care practitioner. Extended wear, there may be increased risks of eye problems, such as irritation, infection, corneal thickening, and corneal ulcers. Therefore, proper contact lens care and periodic checkups are extremely important.

EXTENDED WEAR PATIENTS REQUIRE FREQUENT AND CAREFUL MONITORING OF LENSES AND OCULAR HEALTH TO MINIMIZE COMPLICATIONS.

LENS CARE DIRECTIONS:

Eye care practitioners should review with the patient lens care directions, including both basic lens care information and specific directions from the lens care regimen recommended for the patient.

General Lens Care: (To 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.
• Use the recommended chemical (not heat) system of lens care and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe to 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. Do not put lenses 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.
• Always remove, clean, rinse, enzyme (as recommended by the eye care practitioner) and disinfect lenses according to the directions from the lens care system recommended by the eye care practitioner. The use of enzyme or any cleaning solution does not substitute for disinfection.
• The eye care practitioner should recommend a care system that is appropriate for Hydrasoft contact lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

LENS CARE TABLE

<table>
<thead>
<tr>
<th>Purpose To:</th>
<th>Product Chemical Lens Care System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean</td>
<td>Remu® Multi-Purpose Solution, Miralflow® Extra Strength Daily Cleaner, Opti-Free® Daily Cleaner</td>
</tr>
<tr>
<td>Rinse</td>
<td>Remu® Multi-Purpose Solution, Softwear® Non-Chemical Lens, Opti-Free® Rinsing, Disinfecting and Storage Solution</td>
</tr>
<tr>
<td>Disinfect</td>
<td>Remu® Multi-Purpose Solution, Aosept® Disinfection/Neutralizing Solution, Opti-Free® Rinsing, Disinfecting and Storage Solution</td>
</tr>
<tr>
<td>Store</td>
<td>Remu® Multi-Purpose Solution, Opti-Free® Rinsing, Disinfecting and Storage Solution</td>
</tr>
<tr>
<td>Lubricate &amp; Rewetting</td>
<td>Remu® Rewetting Drops, CLA Vision™ Lens Drops, Opti-Free® Rewetting Drops</td>
</tr>
<tr>
<td>Enzyme</td>
<td>Remu® Enzymatic Cleaner Tablets, ULTRAZYME® Enzymatic Cleaner, Opti-Free® Enzymatic Cleaner</td>
</tr>
</tbody>
</table>

Opti-Free® is a registered trademark of Alcon Laboratories, Inc. Aosept®, Miralflow®, Softwear® and CLA® Vision are registered trademarks of Bausch & Lomb, Inc. Lens Plus®, and ULTRAZYME® are registered trademarks of Allergan, Inc.

• 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 directions.
• Clean one lens first (always the same lens first to avoid contaminating the remaining lens). Rinse the lens thoroughly with recommended saline or disinfection solution to remove cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Replace the lens case at regular intervals as recommended by the lens case manufacturer or the eye care practitioner.

After cleaning, and rinsing, disinfect lenses using the system recommended by the manufacturer and/or eye care practitioner.

• To store lenses, disinfected and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert, the eye care practitioner for information on the storage of lenses.
• After removing the lenses from the lens case, empty, and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the lens case is used again, refill it with storage solution. Replace the lens case at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

Eye care practitioners may recommend a lubricating/removal solution which can be used to wet (lubricate) the lenses while they are being worn to make them more comfortable.

CHEMICAL LENS DISINFECTON (Including Hydrogen Peroxide):

• Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
• After cleaning and rinsing, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the eye care regimen recommended by the lens manufacturer or the eye care practitioner.

When using hydrogen peroxide system lenses, systems must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling.

• Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
• Do not heat the disinfection solution and lenses.
• Leave the lenses in the unopened storage case until ready on the eye care practitioner.

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 in the eye should reduce the potential for irritation.

LENSES DEPOSITS AND USE OF ENZYMATIC CLEANSING:

Enzymatic cleaning may be recommended by the eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed by 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.

LENSES CASE CLEANING AND MAINTENANCE:

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, and rinsed with solution 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 eye care practitioner.

CARE FOR A DRIED OUT (DEHYDRATED) LENS:

If a Hydrasoft lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, apply sterile saline solution before handling.

To rehydrate the lens:

• Handle the lens carefully.
• Place the lens in its storage case and soak the lens in a recommended rinsing and storage solution for at least one hour until it returns to a soft state.
• Clean the lens first, then disinfect the rehydrated lens using a recommended rinsing and storage system.

If after soaking, the lens does not become soft, if the surface remains dry, the lens should not be used unless it has been examined by the eye care practitioner.

CARE FOR A STICKING (NONMOVING) LENS:

If the lens sticks (stays moving or cannot be removed), the patient should be instructed to apply 2 to 3 drops of the recommended lubricating or rewatting 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 more than 5-10 minutes, the patient should immediately consult the eye care practitioner.

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 F LUSH THE EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED:

Each lens is supplied sterile in a glass vial containing buffered isotonic saline solution. The glass vial is labeled with the base curve, diameter, dioptic power (cylinder power and axis are included for a toric lens), manufacturing lot number, and expiration date of the lens.

DO NOT USE IF THE GLASS VIAL OR SHRINK WRAP IS BROKEN OR DAMAGED.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the Hydrasoft contact lens or experienced with the lenses should be reported to:

Attn: Product Services
711 North Road
Scottsdale, New York 14546
(800) 341-2020
Fax (914) 889-5688
www.copervision.com

Part # CV55 0600-2
Rev. Date: 07/2004