

## Hydrasoft® Sphere and Hydrasoft Sphere Thin

Spherical Lenses for Myopia, Hyperopia, and Aphakia

## Hydrasoft® Toric and Hydrasoft® Toric Thin

Astigmatic (Toric) Lenses to Correct Astigmatism

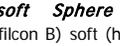
(methafilcon B)

### PACKAGE INSERT

**IMPORTANT:** Please read carefully and keep this information for future use. This package insert is intended for the eye care practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

### SYMBOLS KEY:

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner.
	See Instructions for Wearers
	Use by Date (expiration date)
	Batch Code
	Sterile using Steam Heat

### DESCRIPTION:

**Hydrasoft Sphere and Hydrasoft Sphere Thin** (methafilcon B) soft (hydrophilic) contact lenses are available as spherical lenses. **Hydrasoft Toric and Hydrasoft Toric Thin** (methafilcon B) soft (hydrophilic) contact lenses are available as astigmatic (toric) lenses. The lens material, methafilconB, is a random copolymer of hydroxyethylmethacrylate and methacrylic acid.

**Hydrasoft** contact lenses are hemispherical shells of the following dimensions:

- Diameter: 14.2mm to 15.0mm
- Base Curve: 8.0mm to 9.5mm
- Center Thickness: 0.06mm to 0.65mm (varies with power)

- Spherical Lens Powers: -20.00 to +20.00D
- Daily Wear: -30.00 to +20.00D

- Toric Lens Powers (Daily Wear and Flexible Wear):

- Sphere: -20.00 to +20.00D
- Cylinder: plano to 12.00D
- Axis: 1° to 180°

The physical/optical properties of the lens are:

- Refractive Index: 1.40
- Light Transmittance: 99.6%
- Surface Character: Hydrophilic
- Water Content: 55%
- Oxygen Permeability:  $19.0 \times 10^{-11}$  (cm<sup>2</sup>/sec) (ml O<sub>2</sub>/ml x mmHg) at 25°C (measured by Schema Versatae model 920 connected to a polarographic cell)

### ACTIONS:

When placed on the cornea in its hydrated state, the **Hydrasoft** lens referred to in this package insert acts as a refracting medium to focus light rays on the retina. The design of the toric lens provides a more even surface over the uneven astigmatic cornea and thus helps to focus light rays on the retina.

### INDICATIONS (USES):

1. **Hydrasoft Sphere** lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 1.50 diopters or less that does not interfere with visual acuity.
2. **Hydrasoft Sphere Thin** lenses are indicated for daily wear between removals 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 aphakic and not-aphakic persons with non-diseased eyes.
3. The lenses may be worn by persons who exhibit astigmatism of 1.50 diopters or less that does not interfere with visual acuity.
4. **Hydrasoft Toric** lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes. They may be worn by persons who have astigmatism of 12.00 diopters or less.
5. **Hydrasoft Toric Thin** lenses are indicated for daily wear between removals for cleaning and disinfecting as recommended by the eyecare practitioner. They are indicated for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and not-aphakic person with non-diseased eyes. The lenses may be worn by persons who have astigmatism of 12.00 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 WEARING SCHEDULE).

### CONTRAINDICATIONS (REASONS NOT TO USE):

- Do not use any **Hydrasoft** contact lens referred to in this package insert when any of the following conditions exist:
- Acute and subacute inflammation or infection of the anterior chamber of the eye.
  - Any eye disease, injury, or abnormality 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 lenses.
  - Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated 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.
  - Any active corneal 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:

**Patients should be advised of the following warnings pertaining to contact lens wear:**

- 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, including corneal ulcers, can develop rapidly and lead to **loss of vision; if the following is experienced:**
  - Eye Discomfort,
  - Excessive Tearing,
  - Vision Changes,
  - Loss of Vision,
  - Eye Redness
  - Or Other Eye Problems

**PATIENTS SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THE EYE CARE PRACTITIONER.**

- All contact lens wearers must see their eye care practitioner as directed.
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to 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 tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove the lenses and promptly contact his or her eye care practitioner. It is recommended that contact lens wearers see their Eye Care Practitioner routinely as directed.

### PRECAUTIONS:

#### Special Precautions for Eye Care Practitioners

- Due to the small numbers of patients enrolled in clinical investigation of lenses, 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 eye care 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 should 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 eye care practitioner.
- Visual acuity with high cylinder lenses will be equal to or less than visual acuity with spectacles.
- Aphakic patients should not be fitted with any Hydrasoft

contact lens until the determination is made that the eye 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 discolored. Whenever fluorescein is used in the eyes, the eyes 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 able to promptly remove the lenses or should have 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 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.
  - 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 heat 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 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 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-movement of the lens 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, deodorant, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
  - Do not touch the contact lenses with the finger or hands if the hands are not free of foreign materials, as lens damage may occur.
  - Carefully follow the 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 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. Pour the lens into your hand.
- Do not touch the lens with fingernails.
- Always contact the eye care practitioner before using any medicine 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 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:

- Eyes stinging, burning, or itching (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 the 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 lens in the storage 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 iritis may be present. The patient should be instructed to **keep the 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 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:

CooperVision, Inc.  
711 North Road  
Scottsville, New York 14546  
(716) 385-6810  
Fax (716) 889-5688

#### WEARING SCHEDULE:

The wearing and replacement schedules should be determined by the eye care practitioner. Patients tend to over wear the 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 Hydrasoft 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 Hydrasoft Toric** lenses are indicated for daily wear. The maximum suggested wearing time should be determined by the eye care practitioner.

#### LENS CARE DIRECTIONS:

Eye care 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 patients lens type and wearing schedule:

Day	Hours	Day	Hours
1	6	4	12
2	8	5	14
3	10	6	All waking hours

**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 schedule prescribed 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	
Purpose To:	Product Chemical Lens Care System
Clean	Renu® Multi-Purpose Solution, Miraflow® Extra Strength Daily Cleaner, Opti-Free® Daily Cleaner
Rinse	Renu® Multi-Purpose Solution, SoftWear® Saline, Opti-Free® Rinsing, Disinfecting and Storage Solution
Disinfect	Renu® Multi-Purpose Solution, AOSEPT® Disinfection/Neutralizing Solution, Opti-Free® Rinsing, Disinfecting and Storage Solution
Store	Renu® Multi-Purpose Solution, Opti-Free® Rinsing, Disinfecting and Storage Solution
Lubricate & Rewetting	Renu® Rewetting Drops, CIBA Vision™ Lens Drops, Opti-Free® Rewetting Drops
Enzyme	Renu® Effervescent Enzymatic Cleaner Tablets, ULTRAZYME® Enzymatic Cleaner, Opti-Free® Enzymatic Cleaner

Opti-Free® is a registered trademark of Alcon Laboratories, Inc. AOSEPT®, Miraflow®, SoftWear®, and CIBA® Vision are registered trademarks of CIBA Vision Corp. Renu® is a registered trademark 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 mix-ups), 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. Then repeat the procedure for the second lens.
- **After cleaning**, and rinsing, **disinfect** lenses using the system recommended by the manufacturer and/or eye care practitioner.
- To store lenses, disinfect 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 or 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 lubrication/rewetting solution which can be used to wet (lubricate) the lenses while they are being worn to make them more comfortable.

#### CHEMICAL LENS DISINFECTION (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 lens care systems, lenses **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 to put on the eyes.
- **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.

#### LENS DEPOSITS AND USE OF ENZYMATIC CLEANING:

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.

#### LENS 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 lens care 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 (stops moving or cannot be removed), the patient should be instructed to apply 2 to 3 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 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: FLUSH 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, dioptric 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:

CooperVision, Inc.  
Attn: Product Services  
711 North Road  
Scottsville, New York 14546  
(800) 341-2020  
Fax (585) 889-5688  
[www.coopervision.com](http://www.coopervision.com)