

PACKAGE INSERT

FOR THE

EXTREME H₂O[®] 54% (hioxifilcon D)

Soft Contact Lens
for Daily Wear

**CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER
OF
A LICENSED PRACTITIONER**

Important: Please read carefully and keep this information for future use.

DESCRIPTION OF LENS

Extreme H₂O[®] 54% (hioxifilcon D) soft contact lenses are hemispherical shells and are available as spherical or toric lenses of the following dimensions:

G54 Spheric		G54 Toric	
PARAMETER	VALUE	PARAMETER	VALUE
Diameter:	13.5 mm - 15.5 mm	Diameter:	13.5 mm - 15.5 mm
Center Thickness:	Varies with power	Center Thickness:	Varies with power
Base Curve:	6.0 mm to 10.0 mm	Base Curve:	6.0 mm to 10.0 mm
Power Range:	+20 to -20 diopters	Power Range:	+20 to -20 diopters
		Cylinder Power:	Up to -10.00 diopters
		Axis:	15° to 180° in 15° increments for LC 10° to 180° in 10° increments for MC

The Extreme H₂O[®] 54% (hioxifilcon D) soft contact lens is fabricated from hioxifilcon D, which is a non-ionic, copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (Glycerol Methacrylate, GMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA). It consists of 46% hioxifilcon D and 54% water by weight when immersed in normal saline solution buffered with either sodium bicarbonate or sodium perborate. The lens is available with a blue visibility handling tint, phthalocyanato (2) - (copper).

The Physical/Optical properties of the lenses are:

PROPERTY	VALUE
Refractive Index	1.414 (hydrated)
Light Transmission - tinted	greater than 95%
Water Content	54%
Specific Gravity	1.300 (dry)
Oxygen Permeability (Dk Value)	21 x 10 ⁻¹¹ Fatt Units (cm ² /sec)(ml O ₂ /ml x mm Hg), ANSI Z80:2004 upgraded polarographic method

ACTIONS

In its hydrated state, the Extreme H₂O[®] 54% (hioxifilcon D) soft contact lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina. The toric lens provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus light rays on the retina.

CAUTION

Due to the small number of patients enrolled in clinical investigation of lenses, 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 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 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 eye care practitioner, since individual patient response may vary.

INDICATIONS

The Extreme H₂O[®] 54% (hioxifilcon D) spherical soft contact lens for daily wear is indicated for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit astigmatism of 0.75 Diopters or less that does not interfere with visual acuity.

The Extreme H₂O[®] 54% (hioxifilcon D) toric soft contact lens for daily wear is indicated for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit astigmatism of 10.00 Diopters or less.

Eye care practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfection system.

CONTRAINDICATIONS

DO NOT USE the Extreme H₂O[®] 54% (hioxifilcon D) soft contact lenses when any of the following conditions are present:

- Acute or subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctive, 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 solution which must be used to care for Extreme H₂O[®] 54% soft contact lenses.
- Any active corneal infection (bacterial, fungi, or viral).
- If eyes become red or irritated.
- Patients 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 CONTACT LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use of your lenses 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 ANY DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENSES AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.

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.

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

If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lens and promptly contact his or her eye care practitioner.

ALL CONTACT LENS WEARERS MUST RETURN FOR PERIODIC CHECK-UP VISITS AS RECOMMENDED BY THEIR EYE CARE PRACTITIONER.

PRECAUTIONS

- Clinical studies have demonstrated that contact lenses manufactured from hioxifilcon D are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in this lens material.

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.

- Fluorescein, a yellow dye, should not be used while the lens is on the eye. The lens absorbs this dye and become discolored. Whenever Fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that 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 eye care 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.

- Eye care practitioners should instruct the patient to remove the lens 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 that are fresh and sterile. Never use solutions recommended for conventional hard contact lenses only. Always use FRESH, STERILE, 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 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). Prolonged periods of drying will damage the lens.
Follow the lens care directions in Care for a Dried-Out Dehydrated Dry Lens if the lens surface does become dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions in Care for A Sticking (Non-Moving) 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 lens. 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-based cosmetics are less likely to damage lenses than oil-based.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic 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 Extreme H₂O[®] 54% (hioxifilcon D) soft contact lens 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 hair spray are used while wearing lenses, 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 eye care practitioner about wearing lenses during sporting activities.
- Inform your 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 the hand.
- Do not touch the lens with fingernails.
- Always discard lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the eye care practitioner.
- Always contact the eye care practitioner before using any medicine or medications 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 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 the lens was first placed in the 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 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 LENS.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, **DO NOT PUT THE LENS BACK ON YOUR EYE.** Place the lens in the storage case and contact your 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 the lens then reinsert it.
- After reinsertion, if the problem continues, the patient should **IMMEDIATELY REMOVE THE LENS 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 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 do apply to Extreme H₂O[®] 54% (hioxifilcon D) soft contact lenses. For a detailed description of the fitting techniques, refer to the Professional Fitting Guide, copies of which are available from:

X-Cel Specialty Contacts
7575 Commerce Court
Sarasota, FL 34243 USA

WEARING SCHEDULE

The eye care practitioner should determine the wearing and replacement schedule. Patients tend to over-wear the lenses initially. It is important not to exceed the initial wearing schedule. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular check-ups, as determined by the eye care practitioner, are also extremely important.

X-Cel Specialty Contacts recommends that the lenses be discarded and replaced with new lenses every two weeks. However, the eye care practitioner is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

Extreme H₂O[®] 54% (hioxifilcon D) soft contact lenses are indicated for daily wear. The maximum suggested wearing schedule for Extreme H₂O[®] 54% (hioxifilcon D) soft contact lenses is as follows.

SUGGESTED WEARING SCHEDULE

Days	Continuous Hours	Days	Continuous Hours
1	3	8	8
2	3	9	8
3	4	10	10
4	4	11	12
5	6	12	14
6	6	13	15
7	8	14 and after	All waking hrs

Studies have not been completed to show that Extreme H₂O[®] 54% (hioxifilcon D) soft contact lenses are safe to wear during sleep.

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 patient.

- **Basic Instructions:**

Care of contact lenses 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 lenses. Always use FRESH, STERILE, UNEXPIRED lens care solutions. Use the recommended chemical (no 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 lenses in your 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 disinfecting solution prior to disinfecting the lens. Eye care practitioners may recommend a lubricating/rewetting solution, which can be used to wet (lubricate) the 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 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 storage of the lenses.

- **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 manufacturer; 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 manufacturer or your eye care practitioner.

- **Lens Care Regimen:**

Patients must adhere to the lens care regimen recommended by their eye care practitioner for the Extreme H₂O[®] 54% (hioxifilcon D) 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 lens dries 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.

- **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 non-movement of the lens continues after 15 minutes, the patient should **IMMEDIATELY** consult the eye care practitioner.

- **Storage:**
Extreme H₂O[®] 54% (hioxifilcon D) soft contact lenses must be stored only in the recommended solutions. If left exposed to the air, the lens will dehydrate. If lens dehydrates, reference above section on caring for dried out (dehydrated) dry lenses.
- **Chemical (NOT HEAT) Lens Disinfection:**
 1. Wash and rinse your hands thoroughly BEFORE HANDLING LENS.
 2. CLEAN the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
 3. AFTER CLEANING, disinfect by carefully following the instructions accompanying the disinfecting solution recommended by the eye care professional.
 4. Thoroughly rinse the lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.

Note: DO NOT HEAT THE DISINFECTION SOLUTION AND LENS.

Note: 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.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANER

Enzyme cleaning may be recommended by the eye care 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 lenses and eyes. If these deposits are not removed, they can damage the lenses 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.

LENS CARE PRODUCTS

The eye care practitioner should recommend a care system that is appropriate for hydrophilic soft contact lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

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 FOR AT LEAST 15 TO 30 MINUTES AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

HOW SUPPLIED

Each Extreme H₂O[®] 54% (hioxifilcon D) soft contact lens is supplied sterile in a sealed blister pack containing buffered normal saline solution. The blister pack is labeled with the base curve, power, diameter, manufacturing lot number, and the expiry date of the lens. **Do not use if the blister is damaged or the seal is broken.**

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Extreme H₂O[®] 54% (hioxifilcon D) soft contact lenses or experienced with the lens should be reported to:

X-Cel Specialty Contacts
7575 Commerce Court
Sarasota, FL 34243 USA
1-877-336-2482

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