

WEARER'S INSTRUCTION GUIDE

FOR THE

EXTREME H₂O MONTHLY (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**

*Please read this guide carefully and follow the instructions so
you receive full satisfaction from your lenses.*

CONGRATULATIONS:

You have just received your new **Extreme H₂O Monthly** soft contact lenses (Flat, Median, or Steep base curve). This booklet has been prepared to help you care for them. Please read it carefully and follow the instructions so that you receive full satisfaction from your lenses.

PRACTITIONER:	
ADDRESS:	
TELEPHONE:	
Daily Cleaner:	
Rinsing Solution:	
Disinfecting Solution:	
Enzymatic Cleaner:	
Lubricant/Rewetting Drops:	

INTRODUCTION

Extreme H₂O Monthly (hioxifilcon D) soft contact lenses for daily wear differ from conventional (hard) contact lenses. They are made from a "water-attracting" plastic material, which is referred to as hydrophilic because it has the ability to absorb water. This causes the lenses to become soft and flexible when saturated with water or tears.

Even though **Extreme H2O Monthly** (hioxifilcon D) soft contact lenses may feel immediately comfortable to the eye, you are cautioned to follow the wearing schedule prescribed for you. Do not try to speed up the adaptation process by over wearing the lenses simply because they remain comfortable.

Your eye care practitioner will review with you the instructions for proper hygiene, handling, cleaning, care, and storage of your **Extreme H2O Monthly** (hioxifilcon D) soft contact lenses; and (s) he will make sure that you learn to insert and remove your lenses properly. If you are in doubt about any instructions, ask your eye care practitioner to clarify them.

WEARING RESTRICTIONS AND INDICATIONS

The **Extreme H2O Monthly** (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.

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.

The **Extreme H2O Monthly** (hioxifilcon D) contact lenses described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eye care practitioner. **DO NOT WEAR YOUR EXTREME H2O MONTHLY DAILYWEAR CONTACT LENSES WHILE SLEEPING.**

CONTRAINDICATIONS

DO NOT USE the **Extreme H2O Monthly** (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 Monthly** 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 eye care practitioner.

- Before leaving the eye care practitioner's office, you should be able to promptly remove the lens or should have someone else available who can remove the lens for you.
- You should remove the lens immediately if the eye becomes red or irritated.
- 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 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 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 Monthly** (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 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 you notice any of the above, you should:

- 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. KEEP LENS OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS FOR LENS HANDLING

1. PREPARING THE LENS FOR WEARING

It is essential that you learn to use good hygienic methods in the care and handling of your new **Extreme H2O Monthly** (hioxifilcon D) soft contact lenses. Cleanliness is the first and most important aspect of proper contact lens care.

In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

- ALWAYS wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
- Avoid the use of soaps containing cold cream or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips, and be careful to avoid contact with your fingernails. It is helpful to keep your fingernails short and smooth.

Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2. HANDLING THE LENSES

- Develop the habit of always working with the same lens first to avoid mix-ups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears.

- It is possible that the lens might be inside out; therefore, check the lens by placing it on the index finger and examine its profile. If the edges of the lens tend to point outward, the lens is inside out and should be inverted before placement in eye.

3. PLACING THE LENS ON THE EYE

- The lens should be placed on the tip of your index finger of your dominant hand. Place the middle finger of the same hand close to your lower lash and hold the lid down.
- Use the forefinger or middle finger of the other hand to lift up your upper lid. Look straight ahead and gently place the lens directly on your eye.
- Gently release the lids and blink. The lens will center automatically.
- If there is an initial foreign body sensation, look up to the ceiling and slide the lens off your cornea. Then look down until the lens re-positions itself on the cornea. If the foreign body sensation persists, remove the lens, rinse it with a recommended rinsing solution, and reinsert. If the foreign body sensation still persists, remove the lens and contact your eye care practitioner.
- Use the same technique or reverse hands when applying the other lens.
- If unable to insert the lens using this method, ask your eye care practitioner for an alternate method for lens insertion.

4. CENTERING THE LENS

Very rarely, a lens that is on the cornea will be displaced onto the white part (sclera) of the eye during wear. This can occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens follow either of the following procedures:

- Close your eyelids and gently massage the lens into place through the closed lids.
- Gently manipulate the off-centered lens onto the center of the cornea while the eye is open, using finger pressure on the edge of the upper or lower lid.

5. REMOVING THE LENS

Always remove the same lens first.

- Wash, rinse and dry your hands thoroughly.
- Have your rinsing solution and storage container opened and ready to receive the lenses.

CAUTION: Always be sure the lens is on the cornea before attempting to remove it. Check your vision by covering the other eye. If your vision is blurred, the lens is either on the white part of the eye or it is not on the eye at all.

RECOMMENDED METHODS OF LENS REMOVAL:

Blink Method

The blink method is a safe way to remove the lens while avoiding folding or pinching the lens. Pinching increases the chances of lens splitting or tearing. This method is also useful to those patients who have difficulty touching their fingers to the lens while it is still on their eye.

Seat yourself at a table covered with a clean towel and lean over until you are looking directly down at the surface.

1. Wet eye using lubricating and rewetting drops.
2. Open eye wide and place opposite hand below the eye; palm up (open).
3. Place index finger on the outside edge of the upper lid and press eyelid upward above the contact lens.
4. Press the upper and lower lid margins against the eye, using the index and middle fingers of each hand.
5. At the same time, pull both lids out toward the ear.
6. Attempt to blink. The lens edge will be folded by the pressure of the eyelids. The lens will then pop out of the eye and either be stuck to the lid(s), or you may catch the lens in the palm of your hand.
7. Remove lens from lid(s). Avoid pinching the lens.

Alternate method

1. Insert 1 – 2 drops of lubricating and rewetting solution in eye and wait 15 seconds.
2. Look up and hold down lower lid.
3. Slide lens onto white of eye (sclera) and gently lift off using thumb and forefinger at the widest point (3 & 9 o'clock) of the lens.
4. It is important not to crease or pinch the lens in the center or at the bottom edge to avoid damaging the material.
5. Repeat procedure for the other eye.

GENERAL LENS CARE (clean, rinse, disinfect, etc.)

1. PREPARE THE LENS FOR WEARING

For continued safe and comfortable wearing of your lenses, it is important that you first clean and rinse, and then disinfect (and neutralize if you are using the hydrogen peroxide system) your lenses after each removal, using the care regimen recommended by your eye care practitioner. Cleaning and rinsing is required to remove mucus, secretions, films, or deposits, which may have accumulated during wearing. The ideal time to clean your lenses is immediately after removing them. Disinfecting is necessary to destroy harmful germs.

You should adhere to a recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS in the Package Insert.

If you require only vision correction, but will not or cannot adhere to a recommended care regimen for your lenses, or are unable to place and remove lenses or have someone available to place and remove them, you should not attempt to get and wear contact lenses.

When you first get your lenses, be sure to be able to put the lenses on and remove them while you are in your eye care practitioner's office. At that time you will be provided with a recommended cleaning and disinfecting regimen and instructions and warnings for lens care, handling, cleaning, and disinfecting. Your eye care practitioner should instruct you about appropriate and adequate procedures for your use, and provide you with a copy of the Wearer's Instruction Guide for **Extreme H2O Monthly** (hioxifilcon D) contact lenses.

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use fresh unexpired lens care solution.
- Use the recommended system of chemical (not heat) lens care and carefully follow instructions on solution labeling. 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.

- Always remove, clean, rinse and disinfect your lenses according to the schedule prescribed by your eye care practitioner. The use of an enzyme cleaner or any cleaning solution does not substitute for disinfecting.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- Never rinse your lenses in water from the tap.
There are two reasons for this:
 - You might lose the lens down the drain.
 - Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
- Clean one lens first (always the same lens first to avoid mix-ups) and rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution. Follow the instructions provided in the cleaning solution labeling. Put the lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the system recommended by your eye care practitioner and/or the lens manufacturer. Follow the instructions provided in the disinfecting solution labeling.
- 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 disinfecting, you should consult the package insert or your eye care practitioner for information on storage of your lenses.
- After removing your lenses from the lens case, empty and rinse the lens storage case with solution recommended by lens case manufacturer; then allow the lens case to air dry. When the case is used again; refill it with fresh storage solution. Replace case at regular intervals.

2. CARE FOR A STICKING LENS

If the lens sticks (stops moving) on the eye, apply 2 or 3 drops of a recommended rewetting or lubricating solution. Wait until the lens begins to move freely on your eye before removing it. If non-movement of the lens continues, immediately consult your eye care practitioner.

3. CHEMICAL (NOT HEAT) LENS DISINFECTION

- After you clean and thoroughly rinse your contact lenses, prepare the clean empty lens storage case.
- Wet the lens chambers (sections) with the solution recommended by your eye care practitioner.
- Place each lens in the correct chamber of the lens storage case.
- Fill the chamber with the recommended solution. Completely cover the lens.
- Tightly close both chambers of the lens storage case.
- Follow the directions included with your disinfection solution.
- **WHEN USING CHEMICAL DISINFECTION DO NOT USE HEAT TO DISINFECT YOUR LENSES.**
- Allow your lenses to remain in the disinfection solution for the recommended minimum time for complete disinfection.
- Leave the lenses undisturbed in closed lens case until ready to put on eyes. If longer than one week the lenses should be recycled through the cleaning /disinfection process.
- To remove a lens from the storage case, touch the lens gently with your fingertip and lift it out of the chamber. (BEFORE INSERTING YOUR LENSES, RINSE THOROUGHLY WITH THE RECOMMENDED RINSING SOLUTION).

4. LENS DEPOSITS AND THE USE OF ENZYMATIC CLEANING

The eye care practitioner may recommend enzyme cleaning. 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.

5. LENS CASE CARE

When both lenses have been inserted on your eyes, discard any remaining solution from the storage case. The storage case should be thoroughly rinsed with solution recommended by lens case manufacturer: then allowed to air dry. When the case is used again, refill it with fresh storage solution. Replace lens case at regular intervals.

6. CARE FOR A DEHYDRATED LENS

If your **Extreme H2O Monthly** (hioxifilcon D) Soft Contact Lens is off your eyes and exposed to air for 30 minutes or longer, its surface will dry and gradually become non-wetting. To re-wet your lenses:

- Handle a dried-out lens with great care to avoid breakage. **DO NOT PINCH THE LENS**
- Carefully place the lens in the lens storage case and soak for at least one hour in a recommended disinfection/storage solution.
- After the lens has become wet again, clean and disinfect the lens using the solutions that were recommended by your eye care practitioner.
- If after soaking, the lens does not become soft, or if the surface remains dry, **DO NOT USE THE LENS**, but contact your eye care practitioner.

7. PROFESSIONAL HELP SPECIAL PROBLEMS

Certain symptoms may be early indicators of potentially serious problems such as infection, corneal ulcer, neovascularization, or iritis. Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage. What to do if a problem occurs:

- First, REMOVE THE LENS.
- 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 another foreign body on it and the lens appears undamaged - thoroughly clean, rinse, and disinfect the lens; then reinsert it if the problem has stopped.
- If the problem continues DO NOT put the lens back on your eye. Store it in solution, and IMMEDIATELY consult your eye care practitioner.

A good policy is: *"IF IN DOUBT, TAKE THE LENS OUT"* and promptly consult your eye care practitioner.

WEARING SCHEDULE AND APPOINTMENT SCHEDULE

It is normal to have a short period of adjustment during the first few days of wearing your **Extreme H2O Monthly** (hioxifilcon D) soft contact lenses. Your eye care practitioner will recommend a wearing schedule that is best for you.

Remove, clean and disinfect your lenses any time you notice a change in comfort or vision. If the problem is not eliminated, remove your lenses and contact your eye care practitioner immediately. Examine your eyes in a mirror regularly. If any unusual redness is observed, remove your lenses and contact your eye care practitioner immediately.

Regular check-up examinations by your eye care practitioner are an important part of wearing **Extreme H2O Monthly** (hioxifilcon D) SOFT CONTACT LENSES. Keep all appointments for check-up visits. In the event that you experience any difficulty with your lenses, or you do not understand the instructions given you, do not wait for your next appointment. TELEPHONE YOUR EYE CARE PRACTITIONER IMMEDIATELY.

NOTE: STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE EXTREME H2O MONTHLY (hioxifilcon D) SOFT CONTACT LENSES ARE SAFE TO WEAR DURING SLEEP.

LENS CARE PRODUCTS

NOTE: NEVER USE CONVENTIONAL (HARD) CONTACT LENS SOLUTIONS THAT ARE NOT ALSO RECOMMENDED FOR USE WITH SOFT CONTACT LENSES.

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.

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.

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should:

1. FLUSH THE EYES IMMEDIATELY WITH TAP WATER
2. IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM.

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