

PATIENT INSTRUCTIONS

hioxifilcon A (57% water) for Daily Disposable Soft Contact Lens

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYE CARE PROFESSIONAL OR PRACTITIONER.

CONGRATULATIONS

You have just received your new **hioxifilcon A (57% water)** for daily disposable soft contact lens. Please read and follow these instructions carefully so that you receive full satisfaction from your contact lenses.

PRACTITIONER: _____
ADDRESS: _____
TELEPHONE: _____
LUBRICANT/REWETTING DROPS: _____

INTRODUCTION

With your decision to wear soft (hydrophilic) contact lenses, you have joined a growing number of people who are discovering new pleasures from this important advance in vision correction.

The **hioxifilcon A (57% water)** contact lens is made of a stable, inert, highly purified, hydrophilic (water absorbing) polymer. Fully molded to optical precision in the dry state, the contact lenses hold these qualities in the soft, moist state in which they are suited for your use. Kept moist by the tears in your eyes, the contact lenses are soft and can provide immediate comfort. You are cautioned, however, to follow the initial wearing time schedule prescribed by your eye care professional or practitioner and not to overwear the contact lenses simply because they remain comfortable. Your eye care professional or practitioner will determine your appropriate wearing schedule.

Although soft and pliable, the **hioxifilcon A (57% water)** contact lens is strong and durable. It is designed as a single use daily disposable lens and should be worn one day only. As with all precision devices, proper use will assure you the benefits of convenience, comfort, and confidence in your contact lenses.

Read this Patient Instructions carefully. It contains the information you need to use the contact lenses. If you are in doubt about any instructions, request clarification from your eye care professional or practitioner.

INDICATIONS

The **hioxifilcon A (57% water)** spherical and toric contact lenses are intended to be worn once and then discarded at the end of each wearing period on a daily basis. Start the next wearing period with new lenses. The contact lenses are not intended to be cleaned or disinfected, and should be discarded after a single use.

The **hioxifilcon A (57% water)** contact lens is designed for daily wear (less than 24 hours while awake). The maximum wearing time should be determined by the eye care professional or practitioner based upon your physiological eye condition because individual responses to contact lenses vary. Patients tend to overwear the contact lenses initially. It is important to adhere to the initial maximum wearing schedule established by the eye care professional or practitioner. Studies have not been conducted to show that **hioxifilcon A (57% water)** contact lens is safe to wear during sleep; therefore, remove the contact lenses before sleep. Normal daily wear of the contact lenses assumes a

minimum of 6 hours non-lens wearing per 24-hour period. Optimum individual wearing schedule will vary.

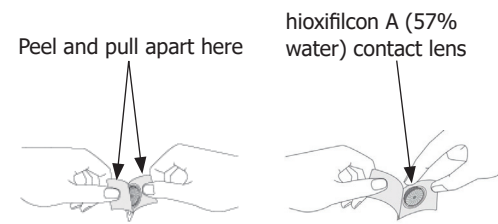
The **hioxifilcon A (57% water)** spherical contact lens is intended for the correction of refractive ametropia (myopia and hyperopia) in aphakic and non-aphakic disease-free eyes of people who may have 1.00 diopter (D) or less of astigmatism that does not interfere with visual acuity.

The **hioxifilcon A (57% water)** Toric contact lens is intended for the correction of refractive ametropia (myopia and hyperopia) in aphakic and non-aphakic disease-free eyes of people who may have 3.00 diopter (D) or less of astigmatism.

HOW SUPPLIED

Each sterile **hioxifilcon A (57% water)** contact lens is shipped immersed in buffered saline solution in a non-traditional packaging system, the Flat Pack which is marked with the information for base curve, dioptric power, diameter, Single Patient Use, Rx Symbol, Sterile Symbol, composition of the lens, manufacturing lot number and expiration date of the lens.

To open the Flat Pack, grasp the top and bottom foil tabs and peel them apart to fully expose the contact lens. Promptly pick up the contact lens with your fingers.



DO NOT WEAR YOUR hioxifilcon A (57% water) CONTACT LENS WHILE SLEEPING.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the **hioxifilcon A (57% water)** contact lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior segment 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 non-aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues that may be induced or exaggerated by wearing contact lenses and/or using contact lens solutions
- Any active corneal infection
- If eyes become red or irritated
- Incomplete corneal healing following eye surgery
- Unable to follow the contact lens wearing schedule or unable to obtain assistance to do so

WARNINGS

You should be advised of the following warnings pertaining to wearing contact lenses:

- Problems with contact lenses could result in **serious injury** to the eyes. It is essential that you follow the directions of the eye care professional or practitioner and all instructions on the labels for proper use of contact lenses. Eye problems, including corneal ulcers, can

develop rapidly and lead to **loss of vision**.

- Daily wear contact lenses are not intended for overnight wear, and you should be instructed not to wear contact lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions increases when daily wear contact lenses are worn overnight.
- Smoking increases the risk of corneal ulcers for contact lens users, especially when contact lenses are worn overnight or while sleeping.^{1,2}
- Do not expose the contact lenses to water while wearing them. Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If contact lenses have been submersed in water such as when swimming in pools, lakes or oceans, discard the contact lenses and replace with new lenses. Ask the eye care professional or practitioner for recommendations about wearing contact lenses during any activity involving water.

- 1 CLAO Journal, January 1996; Volume 22, Number 1, pp. 30-37
- 2 New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

PRECAUTIONS

- DO NOT use the contact lenses if the sterile package has been opened or damaged, or the expiration date has passed.
- Examine the contact lenses to be sure that they are free of any damage or foreign bodies. DO NOT put in the contact lenses if they are in any way damaged.
- Store the contact lenses at room temperature. Do not allow the lenses to freeze.
- If the contact lenses stick (stop moving) on the eyes, follow the recommended directions on "CARE FOR A STICKING (NON-MOVING) LENS". The contact lenses should move freely on the eyes for the continued health of the eyes. If non-movement of the contact lenses continue, you should immediately consult the eye care professional or practitioner.
- No cleaning or disinfecting is necessary for the daily disposable contact lenses. Always discard the used contact lenses. Have replacement contact lenses or glasses ready in case that you need to remove the lenses during the day.
- Always wash and rinse hands before handling contact lenses. Do not get cosmetics, lotions, soaps, creams, deodorant, or sprays in the eyes or on contact lenses. It is best to put on contact lenses before putting on makeup. Water-based cosmetics are less likely to damage contact lenses than oil-based products.
- Handle the contact lenses with care (be careful not to drop them).
- 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.
- Do not touch the contact lenses with fingernails.
- Never use tweezers or other tools to remove the contact lenses from the lens container unless specifically indicated for that use. Pour the lens into a hand.
- Carefully follow the handling, insertion, removal, and wearing instructions in the Patient Instructions for **hioxifilcon A (57% water)** contact lens and those prescribed by the eye care professional or practitioner.
- Never wear the contact lenses beyond the period recommended by the eye care professional or practitioner.
- Avoid all harmful or irritating vapors and fumes while wearing the contact lenses.
- If aerosol products such as hairspray are used while wearing the contact lenses, exercise caution and keep the eyes closed until the spray

has settled.

- Consult the eye care professional or practitioner for instructions on wearing the contact lenses during sports or water activities, or for specific occupations.
- Keep water away from the contact lenses. Avoid showering in contact lenses and remove them before using a hot tub or swimming.
- Inform the medical doctor of being a contact lens wearer.
- Consult the eye care professional or practitioner before using any medicine in the eyes.
- Inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require not to wear contact lenses.
- Follow-up visits are necessary to assure the continued health of the eyes.

ADVERSE REACTIONS

- Eye stinging, burning, itching, or any other pain in the eyes
- Less comfort than when the contact lenses were first put in the eyes
- Continuous foreign body or scratching sensation
- Excessive tearing, unusual eye secretions, redness, reduced visual acuity, blurred vision, rainbows, halos, photophobia, or dry eyes

If any of the above problems occur, you should:

- **Immediately remove the contact lenses.**
- If the discomfort or problem stops, look closely at the contact lenses. If the contact lenses are in any way damaged, do not put them back in the eyes. Discard the contact lenses and replace with new lenses. If the problem continues after putting in new contact lenses, you should **immediately remove the contact lenses and consult the eye care professional or practitioner.**

If the above symptoms continue after removal of the contact lenses or upon putting in new contact lenses, you should **immediately remove the contact lenses and consult the eye care professional or practitioner, or physician**, who must determine the need for examination, treatment or referral without delay. A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present and may progress rapidly. Less serious reactions such as abrasions, epithelial stinging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

HANDLING THE CONTACT LENSES

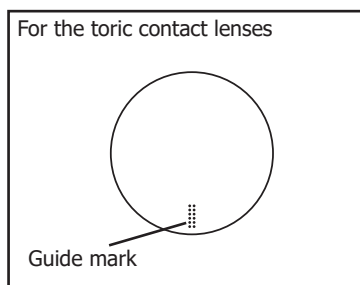
Before Handling the Contact Lenses: Cleanliness is an important aspect of contact lens care.

- Always wash and rinse your hands thoroughly and dry them with a lint-free towel before handling the contact lenses.
- Do not get cosmetics, lotions, soaps, creams, deodorant, or sprays in the eyes or on contact lenses.
- Handle the contact lenses with care. Do not touch the contact lenses with fingernails or other sharp objects.
- Always handle the left and right contact lenses in the same sequence to avoid mixing up the lenses.
- NEVER WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE LENS MAY BE LOST.

Putting in Contact Lenses:

1. Place the contact lens on the tip of the forefinger of your dominant hand with the concave side facing up.
2. Check the profile of the lens to make sure it is not turned inside out.

3. Hold your eyelids wide apart by pulling the upper lid with the forefinger of your non-dominant hand and the lower lid with the middle finger of your dominant hand.
4. Slowly bring the lens up to your eye while looking straight ahead, and gently put the lens on the cornea.
 - Do not press the lens against your eye.
5. Look down, release the upper lid first then the lower lid, and blink gently.
6. Repeat this procedure for the other lens.
 - If your vision is blurred after putting in the contact lenses:
 - If the contact lenses are not centered on the cornea: Look into the mirror, and gently manipulate the edge of the lens to move it onto the cornea while opening your eye. Use finger pressure on the edge of the upper or lower lid until the lens is centered on the cornea.
 - If the contact lenses are centered on the cornea: Remove the lenses. Possible causes are as follows.
 - The lens surface is dirty.
 - The lenses are on the wrong eyes.
 - The lenses have been put inside out onto the eyes.
 - If your vision is still blurred after clearing the problems mentioned above, remove the contact lenses and consult your eye care professional or practitioner.
 - If you feel significant discomfort while wearing the contact lenses, immediately remove the lenses and consult your eye care professional or practitioner.
 - For toric contact lenses, put the lenses on the cornea with the guide mark pointing down.



IF IT IS EASIER, YOU CAN SWITCH HANDS.

There are other methods for putting in the contact lenses. If the above method is difficult for you, the eye care professional or practitioner will provide you with an alternate method.

Removing Contact Lenses:

1. Look upwards while keeping your head straight.
2. Pull down the lower lid with the middle finger of your non-dominant hand and place the forefinger of your dominant hand on the lower edge of the contact lens.
3. Slide the lens down to the lower white part of your eye.
4. Gently pinch the lens between the thumb and forefinger of your dominant hand.
5. Remove the lens.
6. Repeat this procedure for the other lens.

If the above method is difficult for you, the eye care professional or practitioner will provide you with an alternate method.

LENS CARE DIRECTIONS

Basic Instructions:

The **hioxifilcon A (57% water)** contact lens is intended to be worn once and then discarded at the end of each wearing period. Start the next wearing

period with new contact lenses. Have replacement contact lenses or glasses ready at all times.

You should adhere to a recommended care regimen. Failure to follow a recommended care regimen may result in development of serious ocular complications as described in "WARNINGS". If you will not or cannot adhere to a recommended care regimen, or are unable to put in and remove contact lenses or have someone available to put in and remove the lenses for you, you should not wear contact lenses.

When you first get the contact lenses, be sure to put in and remove the lenses while you are in the office of the eye care professional or practitioner. The eye care professional or practitioner should instruct you about appropriate and adequate procedures and products for use, and provide you with a copy of the Patient Instructions for the **hioxifilcon A (57% water)** contact lens.

For safe wearing of contact lenses, you should understand and always practice the lens care routine:

- Always wash, rinse and dry hands before handling contact lenses.
- Do not use saliva for lubricating or rewetting contact lenses.
- Do not put contact lenses in the mouth.
- Never use tap water to rinse the contact lenses. Tap water contains many impurities that can contaminate or damage the contact lenses and may lead to eye infection or injury.
- The eye care professional or practitioner may recommend lubricating or rewetting solution, which can be used to wet (lubricate) contact lenses while you are wearing them to make them more comfortable.

CARE FOR A STICKING (NON-MOVING) LENS

If the contact lenses stick (stop moving) on the eyes, apply a few drops of the recommended lubricating or rewetting solution directly to the eyes and wait until the lenses begin to move freely on the eyes before removing them. If non-movement of the contact lenses continue for more than 10 minutes, you should **immediately** consult the eye care professional or practitioner.

EMERGENCIES

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

FLUSH THE EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE THE CONTACT LENSES PROMPTLY. CONSULT THE EYE CARE PROFESSIONAL OR PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

WHEN TO CALL YOUR PRACTITIONER

Certain symptoms may be early indicators of potentially serious problems. A careful examination of your contact lenses, and professional examination of your eyes, may be required.

Remove the contact lenses by following the instructions outlined in this guide, and call your eye care professional or practitioner if:

- Your eye becomes red and feels irritated or "gritty".
- You notice a change in your vision or see rainbows or halos around objects.
- You experience discomfort and/or sensitivity to lights.

A Good General Policy Is:

"IF IN DOUBT ... REMOVE THE CONTACT LENSES" and contact your eye care professional or practitioner.

Learn and Use Proper lens Care Habits:

- Follow instructions.
- Handle contact lenses properly.
- Learn how to put in and remove the contact lenses.
- Always use fresh contact lenses at the start of the wearing period.

INSTRUCTIONS FOR THE MONOVISION CONTACT LENS WEARERS

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision correction. The benefit of clear near vision in straight ahead and upward gazes may be accompanied by a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. Some patients may experience difficulty in adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks during initial adaptation period. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear the contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of wearing the contact lenses. It is recommended that you only drive with the contact lenses if you pass your state driver's license requirements with the contact lenses.
- Some patients will never be fully comfortable with the vision under low levels of illumination, such as driving at night. If this happens, consult the eye care professional or practitioner for having additional contact lenses or glasses prescribed so that both eyes are corrected for distance when sharp distance vision is required.
- If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses or glasses prescribed. You should discuss your specific visual needs with the eye care professional or practitioner.
- It is important that you follow suggestions of the eye care professional or practitioner for adaptation to monovision correction. You should discuss any concerns that you may have during and after the adaptation period.
- The decision to be fit with monovision correction is most appropriately left to the eye care professional or practitioner in conjunction with you, after carefully considering and discussing your needs.

WEARING SCHEDULE

THE WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PROFESSIONAL OR PRACTITIONER.

The **hioxifilcon A (57% water)** contact lens is indicated for single use daily wear. The suggested maximum wearing time for the contact lenses is:

DAY	1	2	3	4	5	6 and after
HOURS	6	8	10	12	14	All waking hours

STUDIES HAVE NOT BEEN CONDUCTED TO SHOW THAT THE **"hioxifilcon A (57% water)** contact lens" IS SAFE TO WEAR DURING SLEEP.

APPOINTMENT SCHEDULE

Regular check-up examinations by your eye care professional or practitioner are an important part of wearing contact lenses. It is recommended that

you follow directions of your eye care professional or practitioner for follow-up examinations. Keep all appointments for your check-up visits. If you move to a new city, ask your present eye care professional or practitioner to refer you to an eye care professional or practitioner in your new location.

Important:

In the event that you experience any difficulty wearing the contact lenses or you do not understand the instructions given to you, DO NOT WAIT for your next appointment.

TELEPHONE THE EYE CARE PROFESSIONAL OR PRACTITIONER IMMEDIATELY.

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Print Date: 2019-02-22

MDFPUSPIST-009