

PATIENT INSTRUCTION AND WEARER'S GUIDE

OCuSOFT® Amenity[™]

(linofilcon A) Daily Disposable Contact Lenses with HydraSeal™



CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner.

PATIENT INSTRUCTION/WEARER'S GUIDE

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You have just received your daily disposable OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™. This booklet has be prepared to help you care for your lenses. Please read it carefully and follow the instructions.	
Practitioner:	
Address:	
Phone:	

INTRODUCTION

Read this Wearer's Guide carefully. It contains important information for wearing and handling your OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™. If you are in doubt about any instructions, request clarification from your eye care practitioner.

WEARING RESTRICTIONS AND INDICATIONS

OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopters or less that does not interfere with visual acuity.

OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ are to be discarded after each removal.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ when any of the conditions are present:

- 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.
- · Any active corneal infection (bacterial, fungi, or viral).
- If eyes become red or irritated.
- You are unable to follow, or to obtain assistance to follow, lens care regimen or are unable to do so.

WARNINGS

Problems with contact lenses could result in serious injury to the eye.

- Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision if you experience:
 - Eye Discomfort
 - Excessive Tearing
 - Vision Changes
 - Loss of Vision
 - Eye Redness
 - Or Other Eye Problems

You should immediately remove the lenses, and promptly contact your eye care practitioner.

- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the patient's lenses have been submersed in water, such as when swimming in pools, lakes, or oceans the patient should discard them and replace them with a new pair. Patients should be instructed to ask their eye care practitioner (professional) for recommendations about wearing their lenses during any activity involving water.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- You must see your eye care practitioner as directed. Strict compliance with your wearing restrictions, wearing schedule, and follow-up visit schedule should be followed.

PRECAUTIONS

- Daily disposable lenses are to be disposed of once they are removed from your eye. It is important that you have a pair of replacement lenses available if needed. If a lens must be removed from the eye because of dust, a foreign body or other contaminant gets on the lens or the lens becomes dehydrated, the lens should be removed and replaced with a replacement lens.
- 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 lens before putting on makeup. Waterbase cosmetics are less likely to damage lens than
 oil-base.
- Do not touch contact lens with the fingers or hands if the hands are not free of foreign materials, as microscope scratches of the lens may occur, causing distorted vision and/or injury to the eye.
- If aerosol products such as hair spray are used while wearing lens, exercise caution and keep eyes closed until the spray has settled.

- Always handle lens carefully and avoid dropping them.
- Do not expose your contact lenses to water while you are wearing them.
- Avoid all harmful or irritating vapors and fumes while wearing lens.
- Ask your eye care practitioner about wearing your lens during sporting activities.
- Inform the doctor (health care practitioner) about you being a contact lens wearer.
- Never use tweezers or other tools to remove lens from your lens container unless specifically indicated for that use. Pour the lens into your hand.
- Always contact your eye care practitioner before using any medicine or medications in your eyes.
- Always inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lens.

ADVERSE REACTIONS

Eyes stinging, burning, itching (irritation), or other eye pain.

- Comfort is less than when lens was first placed on the eye.
- Feeling that something is in the eye such as a foreign body or scratched area.
- Excessive water (tearing) of the eye.
- Unusual eye secretions.
- · Redness of the eye.
- 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, immediately remove and discard your lens.

- Do not put the lens back on the eye.
- After inserting a new lens, if the problem continues you should keep the lens off the eye and consult your eye care practitioner.
- When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You 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.

PERSONAL CLEANLINESS AND LENS HANDLING

BEFORE HANDLING YOUR DAILY DISPOSABLE LENS:

Cleanliness is the first and most important aspect of proper contact lens care.

Before handling your lens, always wash and rinse your hands thoroughly and dry them with a lint-free towel. Do not use soaps, lotions, cold creams, or perfumes which leave a residue on your hands. Avoid using medications, creams, deodorants, make-up, after shave lotions, or similar items prior to touching your lens. When hair spray is used, the eye must be kept closed until the spray has settled. Take care in handling your lens. Always avoid touching your lens with your fingernails or other sharp objects. Never work directly over a sink with the drain open, as the lens may be lost.

HANDLING AND PLACING THE DAILY DISPOSABLE LENS ON THE EYE:

- Remove the lens from its packaging and examine it to be sure that it is moist, clean, clear and free of any nicks or tears.
- Place the lens on the tip of the index finger of your dominant hand.
- 3. While positioned on your index finger, check to ensure the lens has not turned inside out. To check this, look at the profile of the lens against a light background. If the edge profile appears convex and bowl-shaped, then it is correct. If the lens is inverted, it will flare out at the edge. If the lens is inverted, simply reverse it by using light fingertip pressure. Be sure to avoid damaging the lens with your fingernails.
- 4. Look straight ahead and raise the upper lid with your other index finger.
- 5. Then look down, keep both eyes open and place the lens on the upper white part of the eye.
- 6. Slowly release upper lid, and gently close your eye.
- The lens should center automatically, or it can be moved on center by gentle fingertip pressure through the lids.
- 8. Repeat the above procedure for the second lens.
- 9. If the lens appears to be stuck on your eye, apply a few drops of a recommended lubricating or re-wetting solution to the eye and blink a few times. If the lens does not move freely on your eye, contact your eye care practitioner for further instructions.

There is no single "right way" of putting on a lens. If you find this method of lens placement difficult, your eye care practitioner will suggest another method or provide additional information.

CENTERING THE DAILY DISPOSABLE LENS:

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens on the eye, follow the procedure below.

Using your index finger, gently apply pressure to the lens and slide it back into the cornea. If the lens gets under the upper lid, gently massage the upper lid while looking down and move the lens toward the cornea

REMOVING THE DAILY DISPOSABLE LENS:

Preparation:

- 1. Wash and rinse your hands thoroughly.
- 2. Dry hands with a lint-free towel.
- Check that the lens is centered on the cornea before attempting to remove the lens. Check your vision by covering one eye. If vision is blurry, the lens is off-center. Re-center the lens before attempting to remove it.

Removal:

- To avoid the possibility of lens mix-ups, always begin with the same lens.
- Look up and keep both eyes open.
- 3. Using the middle finger of your dominant hand, gently pull down the lower lid of the first eye. Using the tip of your index finger of the same hand, touch the lens and slide it onto the white of the eye.
- 4. Gently "pinch" the lens between the index finger and the thumb and remove.
- 5. Repeat the procedure for the second eye.
- 6. If the lens cannot be easily moved, apply a few drops of lubricating or re-wetting solution to the eye, blink a few times, and when the lens moves freely on the eye, remove in the manner described above. If the lens still cannot be moved, contact your eye care practitioner for further instruction.
- 7. Upon removal always discard your Daily Disposable lens. Never reuse your Daily Disposable lens

IMPORTANT: Always avoid touching your lens with your fingernails. Use only your fingertips.

If you find this method difficult, your eye care practitioner will suggest another method or provide additional instruction.

CARE FOR A STICKING (NON-MOVING) LENS:

If the lens sticks (cannot be removed), you should apply 3 to 4 drops of the recommended lubricating or re-wetting 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, you should IMMEDIATELY consult your eye care practitioner.

EMERGENCIES

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

Flush eyes immediately with tap water and immediately contact your eye care 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 lens, and professional examination of your eyes, may be required. Remove the lens following the instructions outlined in this guide, and call your eye care practitioner if:

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

A good general policy is: "If in doubt, take the lens out" and contact your eye care practitioner.

INSTRUCTIONS FOR MONOVISION WEARERS

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty 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 as adaptation takes place. 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 these 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 lens wear. It is recommended that you only drive with monovision if you pass your state driver's license requirements with the correction.
- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eye care practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.

If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.

- Some monovision patients require supplemental spectacles to wear over the monovision to provide the clearest vision for critical tasks. You should discuss this with your eye care practitioner.
- It is important that you follow your eye care practitioner's suggestions for adaptation to monovision contact lens therapy. 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 practitioner in conjunction with you, after carefully considering and discussing your needs.

WEARING SCHEDULE

You should follow the wearing schedule determined by your eye care practitioner. The OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ are indicated for daily disposable wear. The maximum suggested wearing time for the lens is:

DAY	HOURS
1	6
2	8
3	10
4	12
5	14
6	All Waking Hours

Do not wear your OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ lenses while sleeping.

APPOINTMENT SCHEDULE

In the event that you experience any difficulty wearing your lens or you do not understand the instructions given to you, do not wait for your next appointment. Call your eye care practitioner immediately.

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