

# **PATIENT INSTRUCTION / WEARER'S GUIDE**

for the

Performance Vision Technologies, Inc.

**ALTIUS™ (ocufilcon D) Performance-Tinted  
Soft (Hydrophilic) Daily Wear Contact Lenses**

***CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON  
THE ORDER OF A LICENSED PRACTICIONER.***

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PRACTITIONER: \_\_\_\_\_

ADDRESS: \_\_\_\_\_  
\_\_\_\_\_

TELEPHONE: \_\_\_\_\_

## **INTRODUCTION:**

Read this wearer's guide carefully. It contains the important information for wearing and handling your ALTIUS™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses. If you have any questions request clarification from your eyecare practitioner.

## **WEARING RESTRICTIONS and INDICATIONS:**

The ALTIUS™ (ocufilcon D) Performance-Tinted SPHERICAL contact lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased that may exhibit astigmatism up to 2.0 diopters that does not interfere with visual acuity.

The ALTIUS™ (ocufilcon D) Performance-Tinted TORIC Soft Contact Lenses for daily wear are indicated for the correction of refractive error in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5.00 diopters.

Eye care practitioners may prescribe any of the above lenses for single use daily disposable wear. When prescribed for daily disposable wear the lens is to be discarded after each removal.

**DO NOT WEAR YOUR ALTIUS™ (OCUFILCON D) SOFT (HYDROPHILIC) DAILY WEAR CONTACT LENSES (TINTED, COLOR) WHILE SLEEPING.**

## **CONTRAINDICATIONS (REASONS NOT TO USE):**

**DO NOT USE** the ALTIUS™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses 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 lens.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.
- Any active corneal infection (bacterial, fungi, or viral)
- If eyes become red or irritated.

## WARNINGS:

- Daily wear lenses are not indicated for overnight wear. You are 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.
- You must see your eyecare practitioner as directed. Strict compliance with your wearing restrictions, wearing schedule, and follow-up visit schedule should be followed.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

WARNING: VISIBLE LIGHT REDUCTION – ALTIUS™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses reduce light transmission into the eye in certain wavelength ranges of the visible spectrum and may alter color perception, similar to tinted sunglasses. *Unlike* sunglasses, contact lenses cannot be removed quickly and easily when complete, normal vision is essential. You should NOT wear ALTIUS™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses in any of the following circumstances:

- In dimly lit environments (e.g. nighttime).
- While operating a motor vehicle or other heavy machinery.
- In other situations where safety is compromised without accurate color vision.

AT ALL TIMES, you should have a pair of general use contact lenses, glasses, or sunglasses available in case environmental or safety conditions change that require removal of the ALTIUS™ contact lenses.

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 Activity – Instruction for Use: Do not expose the contact lenses to water while wearing them.

WARNING: Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the lenses have been submersed in water when swimming in pools, lakes or oceans, the patient should discard them and replace them with a new pair. The patient should ask the eye

care practitioner (professional) for recommendations about wearing the lenses during any activity involving water.

## **PRECAUTIONS:**

- Daily Disposable Lenses are to be disposed of once they are removed from the patient's eye. It is important that patients be instructed to always have available a pair of replacement lenses.
- If a lens becomes dehydrated or must be removed from the eye because of dust, a foreign body or other contaminant, the lens should be removed and replaced with a new lens.
- Carefully follow the handling and wearing instructions in this *Patient Instruction/Wearer's Guide for the ALTIUS™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses* and those prescribed by the eyecare 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 lens before putting on makeup. Water-base 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.
- Never wear lens beyond the period recommended by the eyecare practitioner.
- 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 eyecare practitioner about wearing your lens during sporting activities.
- 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.
- Do not touch the lens with your fingernails.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on (care for 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, you should IMMEDIATELY consult your eyecare practitioner.
- Always contact your eyecare practitioner before using any medicine or medications in your eyes.
- Always inform your health care provider or 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.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You 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 lens was first placed on 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 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 YOUR EYE AND CONSULT YOUR EYECARE 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 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.

*Handling and Placing the Daily Disposable Lens on the Eye:*

- 1) 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.
- 2) 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.
  - 7) 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 rewetting solution to the eye and blink a few times. If the lens does not move freely on your eye, contact your eyecare practitioner for further instructions.

There is no single "right way" of putting on the lens. If you find this method of lens placement difficult, your eyecare 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.
- 3) 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 may be off-center. Re-center the lens before attempting to remove it.

##### Removal:

- 1) To avoid the possibility of lens mix-ups, always begin with the same lens.
- 2) 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 rewetting

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 eyecare practitioner for further instruction.

- 7) Upon removal always discard your daily disposable lens. Never reuse your daily disposable lens.

### **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 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, you should IMMEDIATELY consult your eyecare 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 EYECARE 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 eyecare practitioner if:

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

**IMPORTANT:** If you experience any difficulty wearing your lens or you do not understand the instructions given you, **DO NOT WAIT** for your next appointment. **TELEPHONE YOUR EYECARE PRACTITIONER IMMEDIATELY.**

*A good general policy is:*

**“IF IN DOUBT ... TAKE THE LENS OUT”** and contact your eyecare practitioner.

**Learn and Use Proper lens Care Habits:**

- 1) Follow Instructions.
- 2) Handle Lens Properly.
- 3) Keep Your Lens Clean.

**WEARING SCHEDULE:**

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY YOUR EYECARE PRACTITIONER. The ALTIUS™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses are indicated for single use daily disposable wear. STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE ALTIUS™ (OCUFILCON D) PERFORMANCE-TINTED SOFT (HYDROPHILIC) DAILY WEAR CONTACT LENSES ARE SAFE TO WEAR DURING SLEEP.

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PRINT DATE: 09/2021