

PACKAGE INSERT V201027 Performance OVC (oprifocoon A) Overnight Vision Correction

IMPORTANT

Please read carefully and keep this information for future use.

This package insert is intended for the eye care practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient’s prescribed lenses.

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

Performance OVC (oprifocoon A) Overnight Vision Correction should be fitted only by a contact lens fitter trained and certified in the fitting of conventional (non-reverse geometry) and reverse geometry contact lenses. Nonsterile. Clean and condition lenses prior to use.

DESCRIPTION / INTENDED USE

A rigid-gas-permeable ophthalmic lens intended to be worn directly against the cornea of the eye for orthokeratology (Ortho-K), a procedure where the lens is worn for several hours, typically each night, to modify the curvature of the cornea as an alternative method to correct refractive vision conditions. The device is made of various materials (e.g., cellulose acetate butyrate, polyacrylate-silicone, silicone elastomers) whose main polymer molecules generally do not absorb or attract water but permit diffusion of oxygen (O2) to the ocular surface. This is a reusable device.

Performance OVC (oprifocoon A) Overnight Vision Correction are lathe cut contact lenses with spherical posterior surfaces in blue, green, red and yellow tinted versions. The posterior curve is selected to properly fit an individual eye for orthokeratology and the anterior curve is selected to provide the necessary optical power for a temporary reduction of myopia. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea. Performance OVC (oprifocoon A) Overnight Vision Correction are made from Boston® Equalens®III (oprifocoon A) polymer with a water content of less than 11 percent. The material is available with or without an ultraviolet absorber, Uvinul D-49. The blue tinted lenses contain D&C Green #6 as a color additive. The green tinted lenses contain D&C Green #6 and C.I. Solvent Yellow #18. The red tinted lenses contain D&C Red #17 as a color additive. The yellow tinted lenses contain C.I. Solvent Yellow #18 as a color additive.

LENS PARAMETERS AVAILABLE

Chord Diameter	9.6mm to 11.6mm
Center Thickness	
For low minus lenses	0.20mm to 0.32mm
For plus lenses	0.20mm to 0.32mm
Base Curve	7.30mm to 10.15mm
Reverse Curve	5.0 to 9.0 mm. Steeper than the base curve in proportion to the amount of correction
Alignment Curve 1	7.0 to 9.0 mm. Steeper than the base curve but flatter than the Reverse curve. Generally equal to the Flat K of the cornea being fit
Alignment Curve 2	7.25 to 9.25 mm. Steeper than the base curve but flatter than AC1 and Reverse curve
Peripheral Curves	9.00mm to 15.00mm
Back Vertex Power	+1.50 to –5.00 Diopters

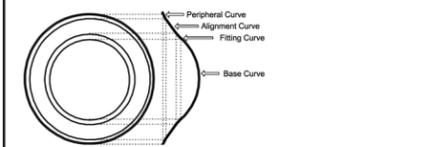


Figure 1: Representation of the reverse geometry lens design.

PHYSICAL PROPERTIES

The physical properties of oprifocoon A

Refractive index	1.423
Light Absorbance (absorbance units/inch)	
Blue (640nm)	10.0
Green (640nm)	4.8
Yellow (420nm)	10.3
Red (525nm)	2.5
Wetting Angle	30 degrees by Captive Bubble
Specific Gravity	1.24
Hardness	114 Rockwell
Water Content	less than 1%
Oxygen Permeability	127* (85**)

* Gas to Gas Method

{ x 10-11 (cm2/sec) (mL O2 x mmHg) } @ 35° C}

** Polarographic Method (ISO/Fatt)

ACTIONS

The Performance OVC (oprifocoon A) Overnight Vision Correction produces a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye, and if the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and completely compensate for myopia.

The posterior surface of regular contact lenses generally aligns with the central cornea and rests directly on the corneal tear layer. Regular contact lenses are designed to cause little or no effect on the cornea but Performance OVC (oprifocoon A) Overnight Vision Correction are designed to purposely flatten the shape of the cornea by applying slight pressure to the center of the cornea when the patient is asleep.

After the lens is removed, the cornea retains its altered shape for all or most of one’s waking hours. The lenses are designed to be worn overnight with removal during the following day. The Performance OVC (oprifocoon A) Overnight Vision Correction must be worn at night on a regular schedule to maintain the orthokeratology effect, or the myopia will revert to the pretreatment level.

INDICATIONS

Performance OVC (oprifocoon A) Overnight Vision Correction for Overnight Wear are indicated for use in the reduction of myopic refractive error in non-diseased eyes. **Intended for patients 19 years of age and older.** The lenses are indicated for overnight wear as part of the Performance OVC (oprifocoon A) Overnight Vision Correction process for the temporary reduction of myopia up to 5.00 diopters with eyes having astigmatism up to 1.50 diopters. The lenses may only be disinfected using a chemical disinfection system.

Note: To maintain the Orthokeratology effect of myopia reduction, overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities (e.g., night driving), visual fluctuations and changes in intended correction.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Performance OVC (oprifocoon A) Overnight Vision Correction when any of the following conditions exist:

- Acute and sub-acute inflammations 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 tears (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa which 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 a solution which is to be used to care for your Performance OVC (oprifocoon A) Overnight Vision Correction.
- Any active corneal infection (bacterial, fungal or viral).

- If eyes become red or irritated.

WARNINGS

The practitioner should provide this warning to the patient.

<p>PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.</p> <p>It is essential that the patient follows the directions of the eye care practitioner and all labeling instructions for proper use of contact lenses and lens care products.</p> <p>EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF THE PATIENT EXPERIENCES:</p> <ul style="list-style-type: none">• Eye Discomfort,• Excessive Tearing,• Vision Changes,• Loss of Vision,• Redness Of The Eye,• Or Other Problems with their Eyes, <p>THEY SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THEIR EYE CARE PRACTITIONER.</p>
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<p>The risk of ulcerative keratitis has been shown to be greater among wearers of extended wear lenses than among wearers of daily wear lenses. The risk among extended wear lens wearers increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning the storage case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens wearers. It is recommended that contact lens wearers see their eye care practitioners twice each year or, if directed, more frequently.</p>

Performance OVC (oprifocoon A) Overnight Vision Correction are to be worn overnight with removal during all or part of each following day. Wearing the lenses continuously (extended wear) presents increased risk, which increases with the number of consecutive days that the lenses are worn between removals. Although the Performance OVC (oprifocoon A) Overnight Vision Correction process prescribes only overnight wear with removal during waking hours, and although the safety risks of overnight wear with removal upon wakening may not be as great as with extended wear, there is still increased risk beginning with the first overnight period.

PRECAUTIONS

Eye Care Practitioner

Clinical studies have demonstrated that lenses for Orthokeratology 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 the material. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all factors that affect lens performance and the patient’s ocular health; including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

<p>The safety and effectiveness of the Performance OVC (oprifocoon A) Overnight Vision Correction have not been clinically studied in adolescent and pediatric subjects.</p>

The potential impact of these factors on the patient’s ocular health should be weighed against the patient’s need for refractive reduction; therefore, the continuing ocular health of the patient, and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

Performance OVC (oprifocoon A) Overnight Vision Correction are supplied **non-sterile in an individual plastic case.** The lens is shipped dry and must be cleaned and conditioned prior to use.

Patient

Patients should be informed of the following precautions

Solution Precautions

- Care of the Performance OVC (oprifocoon A) Overnight Vision Correction may be accomplished with the use of either a twobottle care regimen (separate conditioning solution and a separate cleaning solution) or a one-bottle care regimen (a multi action solution that is an all-in-one-solution). The use of a water rinse is limited to rinsing off the cleaning solution for a two-bottle care regimen (see package insert for instructions) but a water rinse should not be used with a one-bottle care regimen.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions with the Performance OVC (oprifocoon A) Overnight Vision Correction.

- Do not heat the wetting/soaking solution and lenses.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts of the contact lens solutions used.

- Use only a chemical lens care system. Use of a heat (thermal) lens care system can cause damage by warping Performance OVC (oprifocoon A) Overnight Vision Correction.

- 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 solutions for lubricating or wetting lenses.

- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored).

Handling Precautions

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Waterbase cosmetics are less likely to damage lenses than oil-base products.

- Be certain that your fingers or hands are free of foreign material before touching your contact lenses. Microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this booklet and those prescribed by your eyecare practitioner.

- Always handle your lenses carefully and avoid dropping them.

- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour your lens into your hand.

- Do not touch the lens with your fingernails.

- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

Lens Wearing Precautions

- CAUTION: Nonsterile. Clean and condition lenses prior to use.

- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens in the “Instructions for Wearers” booklet. 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 eye care practitioner.
- Never wear your contact lenses beyond the period recommended by your eye care practitioner.

- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products such as sprays are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.

- Lens case should be replaced monthly.

Discuss these topics with each patient:

- Wear of contact lenses during sporting activities

- Use of any medication in your eye

- Importance of adhering to the recommended follow-up schedule to assure the continuing health of your eyes.

- Informing your doctor (health care practitioner) about being a contact lens wearer

- Informing your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that contact lenses not be worn during work hours.

- What should be done if vision is inadequate during the day.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

Patients should be informed that the following problems might occur:

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

- Comfort is less than when lens was first placed on eye.

- Feeling of something in the eye, such as a foreign body or scratched area.

- Excessive watering (tearing) of the eyes

- 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

Please refer to the Clinical Study Section of this package insert for adverse effects observed during the study.

If the patient notices any of these conditions, the patient should be instructed to **IMMEDIATELY REMOVE THE LENSES.**

The patient should be advised to follow these instructions:

- 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 the eye. Place the lens in the storage case and contact the eye care practitioner.

- If the lens has dirt, an eyelash, or other foreign objects on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lens; then reinsert it. Do not use a tap water rinse, use the approved conditioning solution as a rinsing agent.

- If the problem continues, IMMEDIATELY remove the contact lenses and consult the eye care practitioner.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, iritis, persistent stromal edema or GPC (giant papillary conjunctivitis) may be present. The patient 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 including corneal scarring, opacification, blindness or loss of eye.

FITTING

Caution: Performance OVC (oprifocoon A) Overnight Vision Correction should be fitted only by a contact lens fitter trained and certified in the fitting of conventional (non-reverse geometry) and reverse geometry contact lenses.

Conventional methods of fitting rigid contact lenses for orthokeratology DO NOT APPLY to the Performance OVC (oprifocoon A) Overnight Vision Correction Lenses. For a description of fitting techniques, refer to the Fitting Guide for Performance OVC (oprifocoon A) Overnight Vision Correction; copies of the Fitting Guide are available from:

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RECOMMENDED WEARING SCHEDULE

Although many practitioners have developed their own initial wearing schedules, the following sequence

is recommended as a guideline. Patients should be cautioned to limit the wearing schedule as recommended by their eye care practitioner regardless of how comfortable the lenses feel.

Wearing Schedule: On night one lenses should be inserted at a time early enough to achieve 8 to 10 hours of closed eye wearing time (sleep). A well fit lens provides for centration with the eye closed. The effects of lid interaction on blinking and gravity may result in lens decentration during open eye wear. The patient should place the lens(s) in their eye 15 to 20 minutes before going to sleep.

Be aware “when in doubt, take it out”. It is important that the new wearer not sleep in a lens that has a significant foreign body sensation. In the event of foreign body sensation, instruct the patient to remove the lens, clean and re-wet it; and again place the lens in the eye. If the sensation continues, remove the lens. The lens should not be worn.

Appointment Schedule: The patient should report for follow-up evaluation the morning after the first overnight wear. The visit is best scheduled within a few hours of awakening and the patient should report with lenses in place. This visit provides an excellent opportunity to evaluate lens centration and potential lens adherence.

Upon the absence of clinical signs and complications, the patient may be instructed to continue overnight wear of the lenses until the next scheduled follow-up visit.

An alternate daytime wear schedule may be offered at the practitioner’s discretion.

Myopic Reduction Maintenance Lens (Retainer Lens) Schedule

After a period of several days, or when the eyecare practitioner is satisfied that the patient has adapted to the Performance OVC (oprifocoon A) Overnight Vision Correction, the eyecare practitioner may optimize the wearing schedule for an individual patient to monitor the duration of visual improvement. This may continue as long as the patient can see clearly. When it is found that the patient experiences a visual decrement following lens removal, the schedule of overnight wear must be modulated to maintain visual performance.

LENS CARE DIRECTIONS

The lens care products listed below are recommended for use with the Performance OVC (oprifocoon A) Overnight Vision Correction.

Chemical Lens Care System

Two Bottle System:

Boston ADVANCE® Cleaner or Boston® Cleaner

Boston ADVANCE® Comfort Formula

Conditioning (soaking) Solution or Boston®

Conditioning Solution

OR

One Bottle System:

Boston SIMPLUS® Multi-Action Solution

(Removes Protein, Cleans, Disinfects, Conditions, Cushions).

The directions found in the package inserts from these products should be followed. Failure to adhere to these procedures may result in the development of serious ocular complications. A patient should not switch from one care system to another unless it has been determined by the eye care practitioner that this is necessary. Do not mix or alternate the disinfection and storage systems unless so indicated on the product label.

Inform the patient of the following lens care suggestions:

- Always wash and rinse your hands before handling your Performance OVC (oprifocoon A) Overnight Vision Correction
- Never use tweezers or other tools to remove your lenses from the lens container. Pour the lens into your hand.
- Performance OVC (oprifocoon A) Overnight Vision Correction must be both cleaned and disinfected each time you remove them. One procedure does not replace the other. Cleaning is necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs. To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.
- Care of the Performance OVC (oprifocoon A) Overnight

Vision Correction may be accomplished with the use of either a two-bottle care regimen (separate conditioning solution and a separate cleaning solution) or a one-bottle care regimen (a multi action solution that is an all-in-one-solution). The use of a water rinse is limited to rinsing off the cleaning solution for a two-bottle care regimen (see package insert for instructions) but a water rinse should not be used with a one-bottle care regimen.

For a two-bottle system – Clean one lens first. The recommended procedure is to always clean the same lens first to avoid mix-ups. Rinse the lens thoroughly with tap water to remove the cleaning solution. Place the lens into the correct storage chamber and fill the chamber with the recommended disinfecting solution as recommended by your eye care practitioner. Clean and rinse the other lens in the same manner and place it in its chamber with fresh disinfecting solution.

For a one-bottle system – Clean one lens first. The recommended procedure is to always clean the same lens first to avoid mix-ups. Rinse the lens with the one-bottle solution DO NOT USE A TAP WATER RINSE when using a one-bottle system. Place the lens into the correct storage chamber and fill the chamber with the recommended one-bottle disinfecting solution as recommended by your eye care practitioner. Clean and rinse the other lens in the same manner and place it in its chamber with fresh one-bottle disinfecting solution.

- Tightly close the top of each chamber of the lens storage case.

- To disinfect your lenses, leave them in the solution for at least the period indicated on the product label.

- Leave the lenses in the closed storage case until you are ready to put the Performance OVC (oprifocoon A) Overnight Vision Correction in your eyes. DO NOT RINSE THE LENSES WITH TAP WATER PRIOR TO PLACING THE LENSES IN YOUR EYES.

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the case manufacturer, and allowed to air dry. Lens cases should be replaced monthly.

ENZYME CLEANING

The eye care practitioner may recommend enzyme cleaning. Enzyme cleaning does not replace routine cleaning and disinfecting. The patient should carefully follow the instructions in the enzymatic cleaning labeling.

EMERGENCIES

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 and then remove lenses promptly. The patient should

CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each lens is supplied non-sterile in an individual plastic case. The case, packing slip or invoice is marked with the base curve, power in diopters, diameter, center thickness, color, and lot #.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing or experienced with the lenses should be reported immediately to the manufacturer.

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Print Date: Mar 10, 2020

