A Guide to Trouble-Free Contact lens Wear
(Instructions for Use)

Consult an Eye Care Professional for suitability of wear

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<td>Oculus Orthokeratology contact lens</td>
<td>oprifocon A</td>
<td>Indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lenses are indicated for overnight wear 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.</td>
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<td>Oculus Orthokeratology (hexafocon A) contact lens</td>
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**Lens Insertion**

After thoroughly washing and rinsing your hands, and after proper cleaning and conditioning of the lens, follow these steps to insert the lens:

- Remove the lens from its storage compartment.
- Rinse the lens with fresh conditioning solution, if desired.
- Inspect the lens to ensure that it is clean, uniformly wet and free of debris.
- Rub several drops of conditioning solution over the lens surfaces.
- Place the lens on the top of the index finger of your dominant hand. Place the middle finger of the same hand close to the lower lash and hold down the lower lid.
- Use the forefinger or middle finger of your other hand to lift the upper lid and then place the lens on the eye. It is not necessary to press the lens against the eye.
- Gently release the lids and blink. The lens will center automatically. Always verify its proper position by checking your vision immediately after insertion.
- Use the same technique or reverse the hand when inserting the other lens.

There are other methods of lens placement. If the above method is difficult for you, your eye care professional will provide you with an alternative method.
Note: If your vision is blurred after placement of the lens, check for the following:

- The lens is not centered on the eye (see “Centering the Lens”, next in this guide).

- If the lens is centered, remove the lens (see “Lens Removal” section) and check for the following:
  
a. Cosmetic or oil on the lens. Clean, rinse, disinfect, and place on the eye again.

b. The lens is on the wrong eye. If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eye care professional.

## Centering the 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 follow one of the procedures below:

- Close your eyelids and gently massage the lens into place through the closed lids.

  OR

- Gently push the off-centered lens onto the cornea while the eye is open using finger pressure on the upper or lower lid next to the edge of the lens.

## Lens Removal

Before removing your lenses, it is recommended that you have the following items available:

1. A lens storage case
   
   Lens care solutions as recommended by your eye care practitioner.

2. A clean towel
   
   Always remove the same lens first.

   a. Wash, rinse, and dry your hands thoroughly.

   b. There are two suggested methods of lens removal:

### TWO-FINGER METHOD

1. Place a towel under your eye to catch the lens.

2. Place the tip of the forefinger of one hand on the middle of the upper lid margin and the forefinger of the other hand on the middle of the lower lid margin.
3. Press the lid margin inward and then together. The lens should be wedged out of your eye onto your hand or towel.

4. The lens may come out but remain on your eyelid or hand or be decentered onto the white part of your eye. If the latter occurs, recenter the lens onto your cornea before repeating the removal procedure.

**BLINK METHOD**

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

1. Place your index finger at the outer junction of your upper and lower lids, stretch the skin outward and slightly upward. (Do not allow your lid to slide over the lens.)

2. Blink briskly. The lens will be pinched by the pressure of your eyelids and the lens will pop out onto the clean surface of the towel, or you may catch the lens in the palm of your hand.

3. Remove the other lens by following the same procedure.

4. Follow the required lens care procedures described under the heading, CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, STORAGE AND REWETTING/LUBRICATING).

**Note:** If these lens-removal methods are difficult for you, your eye care professional will provide you with an alternative method.

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**Daily Cleaning and Care Regimen**

1. **Basic Instructions**

For continued safe and comfortable wearing of your lenses, it is important that you first **clean** and **rinse**, then **disinfect** your lenses after each removal, using the care regimen recommended by your eye care professional. **Cleaning** and **rinsing** are necessary to remove mucus, secretions, films, or deposits which may have accumulated during wear.

The ideal time to clean your lenses is immediately after removing them. **Disinfecting** is necessary to destroy harmful germs.

You should adhere to the recommended care regimen. Failure to follow the regimen may result in development of serious complications to the eye as discussed in the WARNINGS section above.

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 and do not have someone available to place and remove them for you, you should not attempt to wear contact lenses.

When you first get your lenses, be sure you can place the lenses on your eyes and remove them while you are in your eye care professional’s office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfection. Your eye care professional should instruct you about
appropriate and adequate procedures and products for your use, and provide you with a copy of the guide for the Oculus Orthokeratology 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 solutions.
- Use the recommended system of lens care (chemical not heat) and carefully follow instructions on solution labeling. Different solutions often cannot 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, or if advised by your eye care professional.**
- Always remove, clean, rinse and disinfect your lenses according to the schedule prescribed by your eye care professional. The use of an enzyme or any cleaning solution **does not substitute for disinfection.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- Your Eye Care Professional may recommend lens care products that are appropriate for you to use with your Oculus Orthokeratology contact lenses.
- Clean one lens first (always the same lens first to avoid mix-ups) and rinse the lens thoroughly as recommended by your eye care professional to remove the cleaning solution, mucus, and film from the lens surface. Follow the instructions provided in the cleaning solution labeling. Put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the recommended system by your eye care professional and/or the manufacturer. Follow the instructions provided in the disinfection 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 disinfection, you should consult the Package Insert or your eye care professional for information on storage of your lenses.
- Always keep your lenses completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them again after a few weeks, ask your eye care professional for a recommendation on how to store your lenses.
- Oculus Orthokeratology contact lenses **cannot** be heat (thermally) disinfected.
- After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer or the eye care professional; then allow the lens case to air dry. When the case is used again, refill it with fresh storage
solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eye care professional.

- Your eye care professional may recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.

- Your eye care professional may recommend a weekly enzymatic cleaner which can be used to effectively remove protein deposits from your Oculus Orthokeratology contact lenses.

2. Care for a Sticking (Nonmoving) Lens

If the lens sticks (stops moving/cannot be removed), apply one to three drops of a recommended lubricating or rewetting solution directly to your eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 5 minutes, you should immediately consult your eye care professional.

3. Lens Case Cleaning and Maintenance

Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer or the eye care professional, and allowed to air dry after each use. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eye care professional.

4. Emergencies

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: **FLUSH YOUR EYES IMMEDIATELY WITH TAP WATER, THEN REMOVE YOUR LENSES PROMPTLY, IF POSSIBLE, AND IMMEDIATELY CONTACT YOUR EYECARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

### Schedule for Overnight wear/ Replacement Schedule

Although many professionals 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 professional regardless of how comfortable the lenses feel.

Wearing Schedule: On the first night, lens 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 does not sleep with 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 professional’s discretion.

Myopic Reduction Maintenance Lens (Retainer Lens) Schedule

After a period of several days, or when the eye care professional is satisfied that the patient has adapted to the Oculus Orthokeratology contact lenses, the eye care professional 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.

The recommended replacement schedule for the lens is 1 to 2 years subjected to the condition of the lenses.

**Follow-up Visits**

Appointment Schedule: Your eye care practitioner will schedule a follow-up evaluation after the first overnight wear. The visit is best scheduled within a few hours of awakening and you should report with your lenses in place. This visit provides an excellent opportunity to evaluate lens centration and potential lens adherence.

Assuming the absence of clinical signs and complications, you will be instructed to continue overnight wear of the lenses until the next scheduled follow-up visit. Keeping these appointments is important to maintain good eye health.

**Contraindications/ Warnings/ Precautions/ Adverse Reactions**

1. Do not use the contact lens if any of the following conditions exist: (a) Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids (b) Any active corneal infection (bacterial, fungal, protozoal, or viral) (c) Eye becomes red or irritated

2. Proper use and care of contact lenses and lens care products, including lens cases, are essential for the safe use of these products.

3. If you experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, you should immediately remove your lenses and promptly contact your Eye Care Professional. It is recommended that you see your Eye Care Professional routinely, as directed.

4. Always keep your lenses immersed in recommended storage solution when lenses are not being worn (stored).
5. Avoid all harmful or irritating vapors and fumes while wearing lenses.

6. Ask your Eye Care Professional about wearing lenses during sports activities.

7. Do not share your contact lenses with others.