

PATIENT INFORMATION BOOKLET

AFTER YOUR

Boston® Orthokeratology (oprifocon A) Shaping Lenses

FOR
OVERNIGHT WEAR
FOR

Bausch & Lomb Vision Shaping Treatment™

HAVE BEEN FITTED

Instructions for Wearers of Boston Orthokeratology (oprifocon A) Shaping Lenses for Overnight Wear

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

Boston Orthokeratology (oprifocon A) Shaping Lenses 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.

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General

Clinical studies have demonstrated that Boston Orthokeratology (oprifocon A) Shaping Lenses, for Bausch & Lomb Vision Shaping Treatment™, 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 your ocular health; including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The Boston Orthokeratology (oprifocon A) Shaping Lenses **have not** been clinically studied in adolescent and pediatric subjects.

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

Boston Orthokeratology (oprifocon A) Shaping Lenses are supplied non-sterile in an individual plastic case. The lens is shipped dry and must be cleaned and conditioned prior to use.

Patient

Solution Precautions

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions with the shaping lenses.
- 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 Boston Orthokeratology (oprifocon A) Shaping Lenses.
- 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. Water-base 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 shaping 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 eye care practitioner.
- Always handle your lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove your 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 this 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 cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care practitioner.

Discuss these topics with your eye care practitioner:

- 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.
- During initial weeks of treatment, some patients may experience changes in vision that may require temporary alternate corrective eyewear. This should be discussed with your eye care practitioner.
- Once your vision is fully corrected, you may experience some hours of fluctuation of vision late in the day. If these are bothersome, discuss with your practitioner the possibility of wearing your shaping lenses during those times.
- Ask your eye care practitioner about wearing shaping lenses during sporting activities.
- Ask your eye care practitioner about use of any medication in your eye.

Who Should Know That You Are Wearing Contact Lenses?

- Inform your doctor (health care practitioner) about being a contact lens wearer.
- If you choose to wear your lenses while at work always inform your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear contact lenses during work hours.

ADVERSE EFFECTS

You 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.

If you notice any of the above, **IMMEDIATELY REMOVE YOUR LENSES.**

- 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 your eye. Place the lens in the storage case and contact your eye care practitioner.
- If the lens has dirt, on eyelash, or other foreign objects on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse and disinfect the lens; then reinsert it.
- If the problem continues, you should **IMMEDIATELY** remove the contact lenses and consult your 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. 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 FOR LENS HANDLING:

Preparing the Lens for Wearing:

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper lens care. In particular, your hands should be clean and free of any foreign substance when you handle your lenses. The procedures are:

- Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.

- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- To avoid damaging your lenses, handle them with your fingertips, and be careful to avoid contact with your fingernails. It is helpful to keep your fingernails short and smooth.
- Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

Handling the Lenses:

- Develop the habit of always working with the same lens first to avoid mix-ups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks and tears.

Placing the Lens on the Eye:

- Work over a table, upon which is placed a clean towel.
- Do not place lenses on the eye while working over a sink.

FOR THE RIGHT EYE

- Wet the forefinger of the right hand with a drop of conditioning solution and place the shaping lens on the forefinger of the right hand.
- Place the second finger of the left hand on the middle of the upper lid and press upward firmly.
- Place the second finger of the right hand on the lower lid and press downward firmly.
- Stare into a mirror as though looking through the forefinger holding the shaping lens. You will later learn to do this without a mirror.
- Slowly move the hand to advance the forefinger with the contact lens towards the cornea until the lens touches the cornea and release the lids.
- Release the lid and close the eye for a few seconds.

REPEAT FOR THE LEFT EYE

There are other methods of lens placement. If the above method is difficult for you, your eyecare practitioner will provide you with an alternate method.

Note: If after placement of the lens your vision is blurred, check for the following:

The lens is not centered on the eye (see "Centering the Lens", next section in this booklet).

If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:

- Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
- 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 eyecare practitioner.

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 the procedure below.

- First, locate the lens by pulling away the lids.
- After the lens is found gently press on the lid over the lens while looking away from the direction of the lens.
- Next, look back towards the lens. The lens should center on the cornea.

Removing the Lenses:

- Always remove the same lens first.
- Wash, rinse, and dry your hands thoroughly.
- Work over a table with a clean towel. Do not remove lenses over a sink unless you have first placed a clean towel over the drain.
- Place the right index finger of the right hand at the outer corner of the eye.
- Place the left hand cupped below the eye.
- Open the eyes wide as if to stare.
- Continue to keep the eyes open and pull the lids sideways away from nose.
- Blink quickly and firmly.
- Remove the other lens by following the same procedure.
- Follow the required lens care procedures described under the heading:

CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORING AND REWETTING/LUBRICATING).

Note: If this method of removing your lens is difficult for you, your eye care practitioner will provide you with an alternate method.

Caring For Your Lenses

Basic Instructions:

For continued safe and comfortable wearing of your lenses, it is important that you clean and rinse, then disinfect your lenses after each removal using the care regimen recommended by your eyecare practitioner. Cleaning and rinsing are necessary to remove mucus, secretions, films, or deposits that may have accumulated during wearing. The ideal time to clean, rinse, and disinfect your lenses is immediately after wearing them. Disinfecting is necessary to destroy harmful germs.

You should adhere to a recommended care regimen.

Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS section above.

When you first receive your lenses, practice how to put the lenses on and removing them while you are in your eyecare practitioner'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 eyecare practitioner should instruct you about appropriate and adequate procedures and products for your use.

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse, and dry hands before handling lenses.
- Always use fresh unexpired lens care solutions.

Use the recommended system of lens care, which is chemical (not heat) and carefully follow instructions on solution labeling. Different solutions cannot always 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.

Always remove, clean, rinse, enzyme and disinfect your lenses according to the schedule prescribed by your eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.

To avoid contamination, do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.

The lens care products listed below are recommended by Bausch & Lomb Incorporated for use with your Boston Orthokeratology (opifocan A) Shaping Lenses.

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).

Note: Some solutions may have more than one function, which will be indicated, on the label.

Read the label on the solution bottle, and follow instructions.

Always wash and rinse your hands thoroughly before handling your shaping lenses

Clean

Clean one lens first (always start with the same lens first to avoid mix-ups). Place the lens, front side down, in the palm of the hand and apply several drops of cleaning solution. Using the index finger of the other hand, apply slight pressure in a swirling motion for about 5 seconds. Do not clean the lens by rubbing it between the thumb and index fingers, as this may cause lens warpage.

Rinse

Rinse the lens thoroughly with clean tap water or saline, as directed by your eyecare practitioner, to remove the cleaning solution, mucus, and film from the lens surface. Place that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

Disinfect

After cleaning and rinsing the lens, disinfect them by using the system recommended by your eye care practitioner and/or the lens manufacturer. Follow the instructions provided in the disinfection solution labeling.

Note: Boston Orthokeratology (opifocan A) Shaping Lenses cannot be heat (thermally) disinfected.

Storage

To store lenses, disinfect and leave them in the closed case until ready to wear. If lenses are not to be used immediately following disinfection, you should consult the storage solution package insert or your eyecare practitioner 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 eyecare practitioner for a recommendation on how to store your lenses.

Care of Your Lens Case

Contact lens cases can be a source of bacteria growth. After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with fresh disinfecting solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

Lubricating / Re-wetting

Your eye care practitioner will recommend a lubricating / re-wetting solution for your use. Lubricating / Re-wetting solutions can be used to re-wet (lubricate) your lenses while you are wearing them to make them more comfortable.

Lens Deposits and Use of Enzymatic Cleaning Procedure

Enzyme cleaning may be recommended by your eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well being of your lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does not replace routine cleaning and disinfecting. For enzyme cleaning, you should carefully follow the instructions in the enzymatic cleaning labeling.

Care for a Sticking (Non-Moving) Lens

If the lens is stuck (stops moving) or cannot be removed, you should apply 5 drops of the recommended lubricating or re-wetting solution directly to the eye. Wait until the lens begins to move freely on the eye before removing it.

If non-movement of the lens continues after 30 minutes, you should IMMEDIATELY consult your eye care practitioner.

Emergencies:

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

- FLUSH EYES IMMEDIATELY WITH TAP WATER
- REMOVE YOUR LENSES
- IMMEDIATELY CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

Wearing and Appointment Schedule

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. You should place the lens(s) in your eye 15 to 20 minutes before going to sleep. Your eye care practitioner will advise you if the wearing schedule needs to be changed. 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, remove the lens, clean and re-wet it; and again place the lens in your eye. If the sensation continues, remove the lens. The lens should not be worn.

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.

Appointment Dates

The cornea normally changes within five to eight hours of wear. Your practitioner should modulate your wearing time to determine the MINIMUM wear required for myopic reduction. The average wearing time is between 8 and 10 hours. Attempt to maintain wearing time at this minimal level.

Myopic Reduction Maintenance Lens (Retainer Lens) Schedule

The Retainer Lens schedule should be customized for each patient. The Retainer Lens wearing time begins with the same wearing time required for the last fitted Boston Orthokeratology (orthocon A) Shaping Lenses. After a period of several days, or when the eyecare practitioner is satisfied that the patient has adapted to the Retainer Lenses, the patient may attempt to skip a night of wear 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.

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.

MANUFACTURER

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Print Date: 09/04