PATIENT INFORMATION

Boston XO₂® (hexafocon B)

RIGID GAS PERMEABLE CONTACT LENSES FOR ORTHOKERATOLOGY

Daily Wear

Part 2

After Your Boston XO₂® (hexafocon B) Rigid Gas Permeable Contact Lenses For Orthokeratology Have Been Fitted

Bausch+lomb Boston®

Lenses & Materials



CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a licensed practitioner.

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PRECAUTIONS

Specific Precautions

Clinical studies have demonstrated that contact lenses manufactured from the Boston $XO_2^{\circ 0}$ (hexafocon B) rigid gas permeable lens materials 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 this material. Consequently, when selecting an appropriate lens design and parameter, the eye care practitioner should consider all factors that affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter. The potential impact of these factors should be weighed against your needs. Therefore, your continuing ocular health and lens performance on the eye should be carefully monitored by your prescribing eye care practitioner.

Patients should be instructed to follow the instructions below to reduce the risk of damage to their eyes or lenses:

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 contact lenses.
 - · Do not heat the wetting/soaking solution or 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 (not heat) lens care system. Use of a heat (thermal) lens care system can cause damage by warping Boston XO₂® (hexafocon B) contact 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.
- Do not use tap water as a rinsing agent.
- Tap water, distilled water, or homemade saline should not be used as a substitute for any component in the lens care regimen since they have been associated with an Acanthamoeba keratitis infection.
- 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 your 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-based cosmetics are less likely to damage lenses than oil-based products.
- Be certain that your fingers or hands are free of foreign material before touching your contact lenses as microscopic scratches on 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. To remove the lens from the case, pour the solution containing the lens into the palm of 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

- · If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking (Non-Moving) 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
- 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.
- · Replace your lens case according to the directions given by your eye care practitioner or the labeling that came with your case.

Topics to Discuss with Your Eye Care Practitioner

- · As with any contact lens, follow-up visits are necessary to ensure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.
- Ask your eye care practitioner about wearing lenses during sporting and water-related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection including, but not limited to, Acanthamoeba keratitis.
- · Always contact your eye care practitioner before using any medicine in your eyes

Who Should Know That the Patient is Wearing Contact Lenses

- · Inform your doctor (health care practitioner) about being a contact lens wearer.
- 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 do not wear contact lenses.

ADVERSE REACTIONS

You should be informed that 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.
- · Abnormal feeling of something in the eye (foreign body,
- scratched area). 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).

If you notice any of the above, you should:

İmmediately 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, an 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. After reinsertion, 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 keep the lens off your eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS AND LENS HANDLING

1. 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 contact 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
- · 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.

2. 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.

3. 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.

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 be sure 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 practitioner will provide you with an alternate method.

alternate method.

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

- The lens is not centered on the eye (see "Centering the Lens" section)
- · If the lens is centered, remove the lens (see "Removing the
- Lens" section) and check for the following:

 a. Cosmetics or oils 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 practitioner.

4. Centering the Lens

Very rarely, a lens that is on the comea 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:

 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.

5. Removing the Lens

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

- a) A lens storage case
- b) Lens care system
- c) A clean towel

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.
- · There are two suggested methods of lens removal:

TWO-FINGER METHOD

- a. Place a towel under your eye to catch the lens.
- 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.
- Press the lid margin inward and then together. The lens should be wedged out of your eye onto your hand or towel.
- d. The lens may come out but remain on your eyelid or hand to be decentered onto the white part of your eye. If the latter occurs, re-center the lens onto your comea 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.

- 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.)
- 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.

Note: If these methods for removing your lenses are difficult for you, your eye care practitioner will provide you with an alternate method.

- · 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, STORAGE, AND REWETTING/LUBRICATING).

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

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 practitioner.

Cleaning and rinsing are necessary to remove mucus, secretions, films, or deposits that may have accumulated during wearing. The ideal time to clean your lenses is immediately after removing them. Disinfecting is necessary to destroy harmful germs.

If you require only vision correction, but will not or cannot adhere to a recommended care regimen, or are unable to place and remove lenses or have someone available to place and remove them, you should not attempt to wear contact lenses. When you first receive your lenses, be sure to practice putting on your lenses and removing them while you are in your eye care practitioner's office. At that time, you will be provided with a recommended cleaning and disinfection regimen, as well as instructions and warnings for lens care, handling, cleaning, and disrifection. Your eye care practitioner should instruct you about appropriate and adequate procedures and products for your use.

1. Soaking and Storing Your Lenses

Instructions for Use:

- You should fill your lens case with fresh solution every time you disinfect your lenses, and never "top-off" or re-use solution. You should discard your solution immediately after your lenses have
- You should not expose or store your lenses in or rinse your lens case with any water, such as tap, bottled or distilled, or with any non-sterile solution.

WARNING:

Failure to discard solution from lens case after each use, "topping-off" solution or use of water to care for your lenses may lead to contamination resulting in eye injury and potential loss of vision.

2. Rub and Rinse Time

Instructions for Use:

Follow the complete recommended lens rubbing and rinsing times in the labeling of your solution used for cleaning, disinfecting and soaking your lenses to adequately disinfect your lenses and reduce the risk of contact lens infection.

WARNING:

- You should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect your lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing time may not adequately clean your lenses.
- Never use water, saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfectant can lead to severe infection, vision less set billinghouse.

3. Lens Case Care

Instructions for Use:

- Clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air-drying, be sure that no residual solution remains in the case before allowing it to air-dry.
- Replace your lens case according to the directions given to you by your eye care practitioner or the labeling that came with your case.
- · Contact lens cases can be a source of bacterial growth.

WARNING.

Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh solution so you do not contaminate your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss, or blindness.

Water Activity

Instructions for Use:

Do not expose your contact lenses to water while you are wearing

WARNING-

Water can harbor microorganisms that can lead to severe infection, vision loss, or blindness. If your lenses have been submersed in water when swimming in pools, lakes, or oceans, you should discard them and replace them with a new pair. Ask your eye care practitioner for recommendations about wearing your lenses during any activity involving water.

5. Discard Date on Solution Bottle Instructions for Use:

Discard any remaining solution after the recommended time period indicated on the bottle of solution used for disinfecting and soaking

WARNING:

Using your solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss, or blindness.

6. Basic Instructions

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, 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 eye care practitioner.
 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.
- Never rinse your lenses in water from the tap. There are two
 reasons for this:
 - Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
 - h. You might lose the lens down the drain
- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfecting solution 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 and rinsing, disinfect the lenses using the system recommended by your eye care practitioner. 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 after disinfection, you should consult the labeling of the storage solution for information on lens storage.
- 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 practitioner for a recommendation on how to store your lenses.
- Boston XO₂[®] (hexafocon B) rigid gas permeable contact lenses for orthokeratology cannot be heat (thermally) disinfected.
- After removing your lenses from the lens case, empty, and rinse
 the lens case with solution(s) recommended by the lens case
 manufacturer or the eye care practitioner, 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 practitioner.
- Your eye care practitioner 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.

The lens care products listed in the following chart are recommended by Bausch + Lomb for use with your Boston $XO_2^{\ \oplus}$ (hexafocon B) orthokeratology contact lenses.

Chemical Lens Care

Lens	Care Table
Product Purpose	Lens Care System Chemical (Not Heat)
Clean	Boston ADVANCE® Cleaner
	Boston® Original Cleaner
	Boston SIMPLUS® Multi-Action Solution
Disinfect	Boston ADVANCE® Conditioning Solution
	Boston® Original Conditioning Solution
	Boston SIMPLUS® Multi-Action Solution
Store	Boston ADVANCE® Conditioning Solution
	Boston® Original Conditioning Solution
	Boston SIMPLUS® Multi-Action Solution
Rinse	ScleralFil® Preservative Free Saline Solution
	Boston SIMPLUS® Multi-Action Solution
	Bausch + Lomb Sensitive Eyes® Saline Solution
Lubricate/Rewet	Boston® Rewetting Drops
Weekly Enzymatic Cleaner	Boston® ONE STEP Liquid Enzymatic Cleaner

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution leather and followings regions:

7. 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.

8. Care for a Sticking (Non-Moving) Lens

If the lens sticks (stops moving) or cannot be removed, you should apply 3 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 a. If non-movement of the lens continues after 30 minutes, you should IMMEDIATELY consult your eye care practitioner.

9. Emergencies

It chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, brould: FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPILY. CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

WEARING AND APPOINTMENT SCHEDULES

Prescribed Wearing Schedule Daily Wear

Maximum Wearing Time:

Day	Wearing Time (Hours)
1	
2	
3	
4	
5	
6	
7	
8 and after	

Appointment Schedule

Your appointments are on:

DAY	TIME	DATE	

EYE CARE PRACTITIONER INFORMATION Name

Address _				
Phone Number _				
Emergency Phone	у			

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