PATIENT INFORMATION BOOKLET

Boston XO_2®
(hexafocon B)

Boston XO_2® with Tangible® Hydra-PEG®
(hexafocon B)

Spherical & Aspherical Contact Lenses for Myopia, Hyperopia, and Irregular Corneal Conditions

Bifocal Contact Lenses for Presbyopia

Toric Lenses to Correct Astigmatism in Non-Aphakic and Aphakic Persons

Spherical & Aspherical Scleral Contact Lenses for Myopia, Hyperopia, and Irregular Corneal Conditions

Gas Permeable Contact Lenses for Daily Wear

BAUSCH+LOMB
Boston®
Lenses & Materials

℞ ONLY CAUTION: Federal Law restricts this device to sale by or on the order of a licensed practitioner.

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INTRODUCTION

Boston XO_2® (hexafocon B) and Boston XO_2® (hexafocon B) with Tangible® Hydra-PEG® Contact Lenses are manufactured from a gas permeable plastic material with and without an ultraviolet-absorber. They are intended for ***daily wear use only***. It is essential that you follow the recommended handling, cleaning and storage procedures. Failure to do so may eventually impair the performance of your lenses.

Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses are treated to incorporate Hydra-PEG® Technology (HPT), which is a thin polyethylene glycol (PEG)-based polymer that is covalently (permanently) bonded to the surface of the contact lens and is designed to enhance the surface properties of the contact lens while retaining the mechanical properties of the underlying material. When treated with HPT, the underlying material, hexafocon B, is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (dynamic contact receding angle) compared to untreated lenses. The resulting layer is hydrophilic and approximately 30 nm in thickness.

WEARING RESTRICTIONS AND INDICATIONS

Boston XO_2® (hexafocon B) and Boston XO_2® (hexafocon B) with Tangible® Hydra-PEG® Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism, and presbyopia) in aphakic and non-aphakic persons with non-diseased eyes. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive surgery (e.g., LASIK).

Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses are also indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes.

Note: To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

Furthermore, eyes suffering from certain ocular surface disorders may benefit from the physical protection, aqueous hydrated environment, and the saline bath provided by scleral lens designs.

Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Scleral Contact Lens designs for daily wear are indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject:

1. Cannot be adequately corrected with spectacle lenses.
2. Requires a rigid gas permeable contact lens surface to improve vision.
3. Is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities.

Common causes of corneal distortion include, but are not limited to, corneal infections, trauma, tractions as a result of scar formation secondary to refractive surgery (e.g., LASIK or radial keratotomy), or corneal transplantation. Causes may also include corneal degeneration (e.g., keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Bucklers dystrophy, Cogan's dystrophy).

The Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Scleral Contact Lens designs for daily wear are also indicated for therapeutic use in eyes with ocular surface disease (e.g., ocular Graft-versus-Host disease, Sjögren's syndrome, dry eye syndrome and Filamentary Keratitis), limbal stem cell deficiency (e.g., Stevens-Johnson syndrome, chemical radiation and thermal burns), disorders of the skin (e.g., atopy, ectodermal dysplasia), neurotrophic keratitis (e.g., Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g., anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the Boston® Scleral Lenses may concurrently provide correction of refractive error.

The lenses may be disinfected using a chemical disinfection (not heat) system only.

Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lens described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eye care practitioner. DO NOT WEAR YOUR BOSTON XO_2® AND BOSTON XO_2® WITH TANGIBLE® HYDRA-PEG® CONTACT LENSES WHILE SLEEPING.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses when any of the following conditions exist:

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality, other than irregular corneal conditions as described in the INDICATIONS section, that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if non-aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or using contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for the Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lens material
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes

WARNINGS

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential to follow your eye care practitioner's directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Daily wear lenses are **not** indicated for overnight wear and should not be worn while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, **immediately remove the lenses** and promptly contact your eye care practitioner.

Note: Long term exposure to ultraviolet (UV) radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

WARNING: UV-absorbing contact lenses are **NOT** substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. You should continue to use your protective UV-absorbing eyewear as directed.

PRECAUTIONS

Never reuse the solution. You may store the lenses in the unopened container until ready to dispense, up to a maximum of thirty days from the date of filling (see lens shipping carton label). If the lenses are stored for longer periods of time, they should be cleaned and disinfected with Boston SIMPLUS® Multi-Action Solution.

You may experience a reduction in visibility while wearing these lenses in conditions of low illumination for the following color and center thicknesses:

Lens Type/Color		Center Thickness
Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® –	Blue	>0.65 mm
Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® –	Ice Blue	>0.65 mm
Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® –	Green	>0.55 mm
Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® –	Violet	>0.65 mm

You should carefully adhere to the following care regimen and safety precautions:

- Before leaving the eye care practitioner's office, you should be able to properly remove lenses or should have someone else available who can remove the lenses for you.
- You should remove your lenses immediately if your eyes become red or irritated.
- Different solutions often cannot be used together and not all solutions are safe for use with all lenses. Use only recommended solutions.
  - Do not heat the conditioning/storage solution and/or lenses. Keep them away from extreme heat.
  - Always use **fresh, unexpired** lens care solutions.
  - Always follow directions in the Package Insert for the use of contact lens solutions.
  - Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® 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.
  - Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, they must first be cleaned, rinsed with water, and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. These lenses should be cleaned and disinfected overnight prior to insertion.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a 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, immediately consult your eye care practitioner.
- 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-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, 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 that follow for the Boston XO_2® Contact Lenses and those provided by your eye care practitioner.
- Never wear lenses beyond the period recommended by your eye care practitioner.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- 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.
- Inform your doctor (health care professional) that you wear contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case 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 fingernails.
- Always contact your eye care practitioner before using any medicine in the eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Follow your eye care practitioner's instruction 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 the 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 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 the eye. Place the lens in the storage case and contact your eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, **immediately remove the lenses and consult your eye care practitioner.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You should **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

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 substances 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.
- Handle the lenses with your fingertips and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.
- Start off correctly by getting into the habit of always using proper hygiene 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 or cracks.

3. Placing the Lens on the Eye

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.

Note: 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.

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 in this booklet.
- 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 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.

5. Removing the Lens

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

1) A lens storage case.
2) Appropriate Lens Care System for your Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® from the below Lens Care Chart.
3) 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, re-center 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.

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

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

d. Follow the required lens care procedures described under the heading, LENS CARE DIRECTIONS.

LENS CARE DIRECTIONS

Eye care practitioners should review lens care directions with the patient, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

General Lens Care (First Clean and Rinse, Then Disinfect Lenses)

1. Rub and Rinse Time

Instruction 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:

- Rub and rinse your lenses for the recommended amount of time to help prevent serious eye infections.
- **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 loss or blindness.

2. Soaking and Storing Your Lenses

Instruction for Use:

Use only fresh contact lens disinfecting solution each time you soak (store) your lenses.

WARNING:

Do not reuse or "top-off" old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-off" is the addition of fresh solution to solution that has been sitting in your case.

3. Lens Case Care

Instruction 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 a 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.

4. Water Activity

Instruction for Use:

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

WARNING:

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. 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. If your lenses have been submersed in water, you should thoroughly clean and disinfect them before insertion. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

5. Discard Date on Solution Bottle

Instruction for Use:

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

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

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 the eye care practitioner.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.

Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs. The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfection solution prior to disinfecting the lenses.

Eye care practitioners may recommend a lubricating/rewetting solution, which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

The lens care products listed below are recommended by Bausch + Lomb for use with Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses. Eye care practitioners may recommend alternate products that are appropriate for the patient's use with his or her lens(es).

LENS CARE TABLE: For Boston XO_2® Contact Lenses (Without Tangible® Hydra-PEG® Treatment)

Product Purpose	Lens Care System
Clean	Boston ADVANCE® Cleaner Boston® Cleaner Boston SIMPLUS® Multi-Action Solution
Disinfect	Boston ADVANCE® Conditioning Solution Boston® Conditioning Solution Boston SIMPLUS® Multi-Action Solution
Store	Boston ADVANCE® Conditioning Solution Boston® Conditioning Solution Boston SIMPLUS® Multi-Action Solution
Rinse	ScleralFil® Preservative Free Saline Solution Boston SIMPLUS® Multi-Action Solution
Lubricate/Rewet	Boston® Rewetting Drops
Weekly Enzymatic Cleaner	Boston® ONE STEP Liquid Enzymatic Cleaner

LENS CARE TABLE: For Boston XO_2® Contact Lenses with Tangible® Hydra-PEG® Treatment

Product Purpose	Lens Care System
Clean	Boston SIMPLUS® Multi-Action Solution
Disinfect	Boston SIMPLUS® Multi-Action Solution
Store	Boston SIMPLUS® Multi-Action Solution
Rinse	ScleralFil® Preservative Free Saline Solution Boston SIMPLUS® Multi-Action Solution
Lubricate/Rewet	Boston® Rewetting Drops

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. Enzymatic cleaner **not recommended** for use with lenses coated with Tangible® Hydra-PEG®.

- Clean one lens first (always the same lens first to avoid mix-ups), and rinse the lens thoroughly as recommended by your eye care practitioner 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 above recommended system by your eye care practitioner 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 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 eye care practitioner for a recommendation on how to store your lenses.
- Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® 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 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.
- Your eye care practitioner may recommend a Weekly Enzymatic Cleaner which can be used to effectively remove protein deposits from your Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses. Enzymatic cleaner **not recommended** for use with lenses coated with Tangible® Hydra-PEG®.

7. Care for a Sticking (Non-Moving) 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 practitioner.

8. 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 EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

INSTRUCTIONS FOR THE MONOVISION WEARER

- You should be aware that, as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in all gazes that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to monovision. Symptoms, such as mild blurred vision, dizziness, headaches, and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer is your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations which are not visually demanding. For example, be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state driver's license requirements with monovision correction.
- Some monovision lens wearers will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, discuss with your eye care practitioner whether you should have additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance vision is required.
- If you require very sharp near vision during prolonged close work, you may want to discuss with your eye care practitioner having additional contact lenses prescribed so that both eyes are corrected for near when sharp near vision is required.
- Some monovision lens wearers require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eye care practitioner.
- It is important that you follow your eye care practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- **The decision to be fit with a monovision correction is most appropriately left to the eye care practitioner in conjunction with the patient after carefully considering and discussing your needs.**

CONSIDERATIONS FOR BIFOCAL LENSES

Patients who are considering bifocal contact lenses should be highly motivated and must be informed of the benefits as well as the problems you may encounter while adapting to bifocal contact lens wear.

Your eye care practitioner may discuss the following with you:

A. Adaptation

Both bifocal spectacle and bifocal/multifocal contact lens wearers need to learn to adapt to proper head positioning. The bifocal patient must position the head upright while rotating the eyes downward to read. Once the bifocal patient has adapted, proper positioning becomes effortless.

B. Driving at Night

Bifocal/multifocal contact lens wearers should experience night vision before actually driving while wearing their lenses.

C. Flare at Night

Bifocal/multifocal contact lenses wearers may experience flare at night. This may occur with certain lens designs. With time, bifocal/multifocal contact lens wearers adapt to this situation.

D. Visual Expectation

Bifocal contact lens wearers may experience visual acuities less than could be achieved with bifocal spectacles.

WARNING: Bausch + Lomb Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses are **NOT** intended for overnight (extended) wear.

APPOINTMENT SCHEDULE

Minimum number of hours lenses to be worn at time of appointment: _____

Your appointments are on:

Month	Year	Time	Date

PATIENT/EYE CARE PRACTITIONER INFORMATION

Eye Care Practitioner Information

Practitioner Name: _____

Practice Name: _____

Practitioner Address: _____

Practitioner Phone Number: _____

Recommended Lens Care Regimen: _____

Cleaning Solution: _____

Conditioning Solution: _____

Rewetting Solution: _____

Weekly Enzymatic Cleaner: _____

IMPORTANT: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given to you, DO NOT WAIT for your next appointment. CONTACT YOUR EYE CARE PRACTITIONER IMMEDIATELY.

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609 USA
www.bauschsvp.com
1-800-333-4730

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PACKAGE INSERT

Boston XO_2®
(hexafocon B)

Boston XO_2® with Tangible® Hydra-PEG®
(hexafocon B)

Spherical & Aspherical Contact Lenses for Myopia, Hyperopia, and Irregular Corneal Conditions

Bifocal Contact Lenses for Presbyopia

Toric Lenses to Correct Astigmatism in Non-Aphakic and Aphakic Persons

Spherical & Aspherical Scleral Contact Lenses for Myopia, Hyperopia, and Irregular Corneal Conditions

Gas Permeable Contact Lenses for Daily Wear

BAUSCH + LOMB
Boston®
Lenses & Materials

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 lens.

℞ ONLY CAUTION: Federal Law restricts this device to sale by or on the order of a licensed practitioner.

DESCRIPTION

Boston XO_2® (hexafocon B) and Boston XO_2® (hexafocon B) with Tangible® Hydra-PEG® are manufactured from a gas permeable contact lens material composed of siloxanyl fluoromethacrylate copolymer. Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® is available with or without an ultraviolet absorber (Uvinul D-49 or MHB).

Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses are treated to incorporate Hydra-PEG® Technology (HPT), which is a thin polyethylene glycol (PEG)-based polymer that is covalently (permanently) bonded to the surface of the contact lens and is designed to enhance the surface properties of the contact lens while retaining the mechanical properties of the underlying material. When treated with HPT, the underlying material, hexafocon B, is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (dynamic contact receding angle) compared to untreated lenses. The resulting layer is hydrophilic and approximately 30 nm in thickness.

Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses are hemispherical shells of the following dimensions:

Spherical Lens Design	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 21.0 mm
Base Curve Range	5.00 mm to 9.00 mm in 0.01 mm increments
Aspherical Lens Designs (Manufacture of these lenses in Boston XO_2® (hexafocon B) and Boston XO_2® (hexafocon B) with Tangible® Hydra-PEG® material is authorized for licensed labs only)	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 21.0 mm
Base Curve Range	6.00 mm to 9.20 mm in 0.01 mm increments
Bifocal Lens Designs (Manufacture of these lenses in Boston XO_2® (hexafocon B) and Boston XO_2® (hexafocon B) with Tangible® Hydra-PEG® material is authorized for licensed labs only)	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 21.0 mm
Base Curve Range	6.30 mm to 9.50 mm in 0.01 mm increments
Segment Heights	-2.00 mm to +1.00 mm in 0.5 mm increments
Add Powers	+1.00D to +3.75D in 0.5D increments
Prism Ballast	0.5 to 3.5 prism diopters in 0.5D increments
Toric Lens Designs	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 21.0 mm
Base Curve Range	6.80 mm to 9.50 mm in 0.01 mm increments
Toricity	Up to 9.00 Diopters
Irregular Cornea Lens Designs (keratoconus, pellucid marginal degeneration, post-penetrating keratoplasty or post-refractive surgery (e.g., LASIK))	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 21.0 mm
Base Curve Range	4.00 mm to 9.00 mm in 0.01 mm increments
Base Optic Zone	5.00 mm to 9.00 mm in 0.01 mm increments
Scleral Contact Lens Designs	
Power Range	+35.00D to -25.00D in 0.25D increments
Diameter	16.00 mm to 21.00 mm
Normalized Vaults	2.50 mm to 6.00 mm

The lenses described in the first column can have a center thickness of 0.07 mm to 0.65 mm that will vary with lens design, power and diameter.

Physical/Optical Properties of Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lens/Material:

The tinted lenses contain the following color additives:

Color	Color Additive
Blue	D & C Green No. 6
Ice Blue	D & C Green No. 6
Violet	D & C Violet No. 2
Green	D & C Green No. 6 C.I. Solvent Yellow No. 18

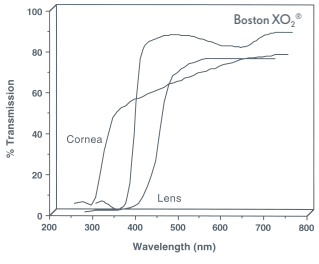
Specific Gravity	1.19
Refractive Index	1.424

Light Transmittance*

Tint	Transmittance
Blue	83%
Ice Blue	90%
Violet	90%
Green	90%
Surface Character	Hydrophobic
Wetting Angle	38°
Wetting Angle w/Hydra-PEG	10°
Water Content	<1%
Oxygen Permeability:	
Edge Corrected	141**
Non-Edge Corrected	161**

*Average CIE Luminous Y Transmittance (381 nm - 780 nm) (lens center thickness = 0.65 mm)

**ISO/Fatt Method:
DK Units = $x\ 10^{-11}$ ($cm^3\ O_2$)(cm)/[(sec)(cm^2)(mmHg)] @ 35°C



Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® - 0.07 mm thick Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lens/Material (Ice Blue)

Cornea - Human cornea from a 24-year-old person as described in Lerman, S., *Radiant Energy and the Eye*, MacMillan, New York, 1980, p. 58.

Crystalline Lens - Human crystalline lens from a 25-year-old person as described in Waxler, M., Hitchins, V.M., *Optical Radiation and Visual Health*, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5.

Note: Long term exposure to ultraviolet (UV) radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

WARNING: UV-absorbing contact lenses are **NOT** substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

ACTIONS

Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses when placed on the cornea act as a refracting medium to focus light rays on the retina.

INDICATIONS (USES)

Boston XO_2® (hexafocon B) and Boston XO_2® (hexafocon B) with Tangible® Hydra-PEG® Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism, and presbyopia) in aphakic and non-aphakic persons with non-diseased eyes. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive surgery (e.g., LASIK).

Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses are also indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes.

Note: To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

Furthermore, eyes suffering from certain ocular surface disorders may benefit from the physical protection, aqueous hydrated environment, and the saline bath provided by scleral lens designs.

Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Scleral Contact Lens designs for daily wear are indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject:

1. Cannot be adequately corrected with spectacle lenses.
2. Requires a rigid gas permeable contact lens surface to improve vision.
3. Is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities.

Common causes of corneal distortion include but are not limited to corneal infections, trauma, tractions as a result of scar formation secondary to refractive surgery (e.g., LASIK or radial keratotomy) or corneal transplantation. Causes may also include corneal degeneration (e.g., keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Bucklers dystrophy, Cogan's dystrophy).

The Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Scleral Contact Lens designs for daily wear are also indicated for therapeutic use in eyes with ocular surface disease (e.g., ocular Graft-versus-Host disease, Sjögren's syndrome, dry eye syndrome and Filamentary Keratitis), limbal stem cell deficiency (e.g., Stevens-Johnson syndrome, chemical radiation and thermal burns), disorders of the skin (e.g., atopy, ectodermal dysplasia), neurotrophic keratitis (e.g., Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g., anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the Boston® Scleral Lenses may concurrently provide correction of refractive error.

The lenses may be disinfected using a chemical disinfection (not heat) system only.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses when any of the following conditions exist:

- Acute or subacute inflammation of the anterior chamber of the eye
- Any eye disease, injury, or abnormality, other than irregular corneal conditions as described in the INDICATIONS section, that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if non-aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or using contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for the Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lens materials.
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes

WARNINGS

Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that patients follow their eye care practitioner's directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Daily wear lenses are **not** indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these daily wear lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove lenses** and promptly contact his or her eye care practitioner.

PRECAUTIONS

Practitioner Note: Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses are not sterile when shipped from the Authorized Boston® Manufacturer. Prior to dispensing, clean, and disinfect the lens(es) according to the appropriate lens care regimen.

- Never reuse the solution. You may store the lenses in the unopened container until ready to dispense, up to a maximum of thirty days from the date of filling (see lens shipping carton label). If the lenses are stored for longer periods of time, they should be cleaned and disinfected with Boston SIMPLUS® Multi-Action Solution.
- Patients may experience a reduction in visibility while wearing these lenses in conditions of low illumination for the following color and center thickness:

Lens Type/Color		Center Thickness
Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® –	Blue	>0.65 mm
Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® –	Ice Blue	>0.65 mm
Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® –	Green	>0.55 mm
Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® –	Violet	>0.65 mm

Special Precautions for Eye Care Practitioners:

- When wet shipped, Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses are packaged non-sterile in a preserved aqueous solution, either Boston SIMPLUS® Multi-Action Solution or Boston ADVANCE® Conditioning Solution. Boston SIMPLUS® Multi-Action Solution contains poloxamine, hydroxyalkyl phosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, glucam, and preserved with polyaminopropyl biguanide (0.0005%), chlorhexidine gluconate (0.003%). Boston ADVANCE® Conditioning Solution contains polyaminopropyl biguanide (0.0005%), chlorhexidine gluconate (0.003%), and edetate disodium (0.05%) as preservatives. If the patient has experienced a prior history of allergy to any of the ingredients in Boston SIMPLUS® Multi-Action Solution or Boston ADVANCE® Conditioning Solution, remove the lens from the solution and soak for 24 hours in unpreserved saline solution prior to cleaning, disinfecting, and dispensing.
- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.
- Patients who wear contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Aphakic patients should not be fitted with Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eye care practitioner's office, the patient should be able to properly remove lenses or should have someone else available who can remove the lenses for him or her.
- Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- The presence of the UV-absorber in the Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lens materials may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Professional Fitting and Information Guide for detailed instructions.)

Eye care practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
  - Do not heat the conditioning/storage solution and/or lenses. Keep them away from extreme heat.
  - Always use **fresh, unexpired** lens care solutions.
  - Always follow directions in the Package Inserts for the use of contact lens solutions.
  - Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® 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.
  - Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, they must first be cleaned, rinsed

with water, and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfected prior to insertion.

- Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses must be store in the lens storage case with the recommended solutions. Dry storage is not recommended.

- If the lens sticks (stops moving) on the eye, the patient should be instructed to follow the recommended directions on Care for a 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, the patient should be instructed to immediately consult his or her eye care practitioner.
- 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-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, 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 the Patient Information Booklet for the Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses and in those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Patients should be advised 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.
- Instruct patient to inform his or her doctor (health care professional) that the patient wears contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case 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 fingernails.
- Instruct the patient to contact his or her eye care practitioner before using any medicine in the eyes.
- Instruct the patient to inform his or her employer that he or she wears contact lenses. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS

The patient 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 the 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 the patient notices any of the above, he or she should be instructed to:

- **Immediately remove lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, the lens should not be placed 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 body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, **immediately remove the lenses and consult the eye care practitioner**.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis 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.

FITTING

For detailed descriptions of the conventional fitting techniques and special fitting considerations for the Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses, refer to the Boston XO_2® Professional Fitting and Information Guide, copies of which are available from:

Practitioner Marketing Representative
Boston Products Group of Bausch + Lomb
1400 North Goodman Street
Rochester, NY 14609 USA
www.bauschsvp.com
1-800-225-1241

Professional Fitting Guides are also available through your Authorized Boston® Manufacturer.

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care practitioner. Patients tend to overwear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, are also extremely important. Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses are indicated for **daily wear**.

WARNING: Bausch + Lomb Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses are **NOT** intended for overnight (extended) wear.

LENS CARE DIRECTIONS

Eye care practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

General Lens Care (First Clean and Rinse, Then Disinfect Lenses)

1. Rub and Rinse Time

Instruction 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:

- Rub and rinse your lenses for the recommended amount of time to help prevent serious eye infections.
- **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 loss or blindness.

2. Soaking and Storing Your Lenses

Instruction for Use:

Use only fresh contact lens disinfecting solution each time you soak (store) your lenses.

WARNING:

Do not reuse or "top-off" old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-off" is the addition of fresh solution to solution that has been sitting in your case.

3. Lens Case Care

Instruction 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 a 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.

4. Water Activity

Instruction for Use:

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

WARNING:

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. 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. If your lenses have been submersed in water, you should thoroughly clean and disinfect them before insertion. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

5. Discard Date on Solution Bottle

Instruction for Use:

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

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

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 the eye care practitioner.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.

Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs. The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfection solution prior to disinfecting the lenses.

Eye care practitioners may recommend a lubricating/rewetting solution, which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

The lens care products listed below are recommended by Bausch + Lomb for use with Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses. Eye care practitioners may recommend alternate products that are appropriate for the patient's use with his or her lens(es).

LENS CARE TABLE: For Boston XO_2® Contact Lenses (Without Tangible® Hydra-PEG® Treatment)

Product Purpose	Lens Care System
Clean	Boston ADVANCE® Cleaner Boston® Cleaner Boston SIMPLUS® Multi-Action Solution
Disinfect	Boston ADVANCE® Conditioning Solution Boston® Conditioning Solution Boston SIMPLUS® Multi-Action Solution
Store	Boston ADVANCE® Conditioning Solution Boston® Conditioning Solution Boston SIMPLUS® Multi-Action Solution
Rinse	ScleralFil® Preservative Free Saline Solution Boston SIMPLUS® Multi-Action Solution
Lubricate/Rewet	Boston® Rewetting Drops
Weekly Enzymatic Cleaner	Boston® ONE STEP Liquid Enzymatic Cleaner

LENS CARE TABLE: For Boston XO_2® Contact Lenses with Tangible® Hydra-PEG® Treatment

Product Purpose	Lens Care System
Clean	Boston SIMPLUS® Multi-Action Solution
Disinfect	Boston SIMPLUS® Multi-Action Solution
Store	Boston SIMPLUS® Multi-Action Solution
Rinse	ScleralFil® Preservative Free Saline Solution Boston SIMPLUS® Multi-Action Solution
Lubricate/Rewet	Boston® Rewetting Drops

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. Enzymatic cleaner **not recommended** for use with lenses coated with Tangible® Hydra-PEG®.

- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly as directed by your eye care practitioner to remove the cleaning solution, mucus, and film from the lens surface, and 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 system recommended by the manufacturer and/or the eye care practitioner. Follow the instructions provided in the disinfecting solution packaging.

- 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, the patient should be instructed to consult the Package Insert or the eye care practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air-dry. When the case is used again, refill it with fresh storage solution. Replace the lens case at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.
- Eye care practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- Eye care practitioners may recommend a Weekly Enzymatic Cleaner which can be used to effectively remove protein deposits from Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses. Enzymatic cleaner **not recommended** for use with lenses coated with Tangible® Hydra-PEG®.
- Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses **cannot** be heat (thermally) disinfected.

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

If the lens sticks (stops moving/cannot be removed), the patient should be instructed to apply one to three drops of a 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 5 minutes, the patient should immediately consult the eye care practitioner.

8. Emergencies

The patients should be informed that 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, THEN REMOVE LENSES PROMPTLY, IF POSSIBLE, AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

HOW SUPPLIED

Each lens is supplied (non-sterile) in a plastic lens storage case, dry or in solution (Boston ADVANCE® Conditioning Solution or Boston SIMPLUS® Multi-Action Solution). The case is labeled with the base curve, diopter power, diameter, center thickness, color, UV-absorber (if present), and lot number. Additional parameters of add power, segment height, prism ballast, and truncation may be included for bifocal lenses.

REPORTING OF ADVERSE REACTIONS

All serious adverse reactions observed in patients wearing Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses or adverse experiences with the lenses should be reported to:

Consumer Affairs
Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609 USA
1-800-333-4730

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