PACKAGE INSERT

Boston® XO_2
(hexafocon B)

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

Bifocal Contact Lenses for Presbyopia

Toric Lenses to Correct Astigmatism in Not aphakic and Aphakic Persons

Gas Permeable Contact Lenses For Daily Wear

IMPORTANT:
Please read carefully and keep this information for future use. This package insert is intended for the eyecare practitioner, but should be made available to patients upon request. The eyecare practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

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

DESCRIPTION

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

Boston XO_2 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 *(Some of these designs are patented; manufacture of these lenses in Boston XO_2 (hexafocon B) 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 *(Some of these designs are patented; manufacture of these lenses in Boston XO_2 (hexafocon B) 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 (e.g. LASIK) surgery)	
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

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

Physical/Optical Properties of Boston XO_2 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*	

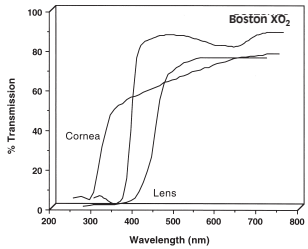
Tint	Transmittance
Blue	83%
Ice Blue	90%
Violet	90%
Green	90%

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

Surface Character	Hydrophobic
Wetting Angle	38°
Water Content	<1%
Oxygen Permeability:	
Edge Corrected	141**
Non Edge Corrected	161**

**ISO/Fatt Method:

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



Boston XO_2 - 0.07 mm thick Boston XO_2 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 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 Contact Lenses when placed on the cornea act as a refracting medium to focus light rays on the retina. The toric lens provides a more even surface over the uneven astigmatic cornea and thus helps to focus light rays on the retina.

INDICATIONS (USES)

Boston XO_2 Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not aphakic persons with non-diseased eyes. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a gas permeable contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery. The lenses may be disinfected using a chemical disinfection system only.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE Boston XO_2 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 keratoconus, that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if not 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 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 eyecare 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 eyecare practitioner.

PRECAUTIONS

Practitioner Note: Boston XO_2 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.

- 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 - Blue	> 0.65 mm
Boston XO_2 - Ice Blue	> 0.65 mm
Boston XO_2 - Green	> 0.55 mm
Boston XO_2 - Violet	> 0.65 mm

Special Precautions for Eyecare Practitioners:

- 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 eyecare 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 eyecare 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 Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eyecare 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.
- Eyecare practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

- The presence of the ultraviolet (UV) light absorber in the Boston XO_2 contact lens materials may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Fitting Guide for detailed instructions.)

Eyecare 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 Contact Lenses.
  - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
  - Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
  - 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.
- If the lens sticks (stops moving) on the eye, the patient should be instructed to follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, the patient should be instructed to immediately consult his or her eyecare 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 Instructions for the Boston XO_2 Contact Lenses and in those prescribed by the eyecare practitioner.
- Never wear lenses beyond the period recommended by the eyecare 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.
- Instruct patient to ask his or her eyecare practitioner about wearing lenses during water activities and other sports.
- Instruct patient to inform his or her health care practitioner (doctor) 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. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Instruct the patient to contact his or her eyecare 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 EFFECTS

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, 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 eyecare 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 eyecare 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 (hexafocon B) 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
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 eyecare practitioner. Patients tend to overwear the lenses initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

Boston XO_2 Contact Lenses are indicated for daily wear. The suggested wearing time for these lenses is:

DAY	WEARING TIME (Hours)*
1	4 to 8 hours
2	6 to 10 hours
3	8 to 14 hours
4	10 to 15 hours
5	12 to All Waking Hours
6 and after	All Waking Hours

*if the lenses continue to be well-tolerated.

LENS CARE DIRECTIONS

WARNING: Boston XO_2 Contact Lenses are **NOT** intended for overnight (extended) wear.

Eyecare 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)

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

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

LENS CARE TABLE

Product Purpose	Lens Care System Chemical (Not Heat)
Clean	Boston ADVANCE® Cleaner or Boston® Cleaner
Disinfect	Boston ADVANCE® Comfort Formula Conditioning Solution or Boston® Conditioning Solution
Store	Boston ADVANCE Comfort Formula Conditioning Solution or Boston Conditioning Solution
Multi-Action (Clean, Condition, Disinfect, Rinse and Cushion)	Boston SIMPLUS® Multi-Action 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 bottle, and follow instructions.

- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly as directed by your eyecare 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 eyecare 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 eyecare 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 storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.
- Eyecare 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.
- Eyecare practitioners may recommend a weekly enzymatic cleaner which can be used to effectively remove protein deposits from Boston XO_2 Contact Lenses.
- Boston XO_2 Contact Lenses **cannot** be heat (thermally) disinfected.

LENS CASE CLEANING AND MAINTENANCE

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

CARE FOR A STICKING (NONMOVING) 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 nonmovement of the lens continues after 5 minutes, the patient should immediately consult the eyecare practitioner.

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 EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each lens is supplied (nonsterile) in a plastic lens storage case. 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 Contact Lenses or adverse experiences with the lenses should be reported to:

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

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