
PACKAGE INSERT

BOSTON XO[®] (hexafocon A) RIGID GAS PERMEABLE CONTACT LENSES FOR ORTHOKERATOLOGY

Daily Wear

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.

CAUTION:

Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed practitioner.

DESCRIPTION - BOSTON XO

BOSTON XO Rigid Gas Permeable (RGP) contact lenses for daily wear orthokeratology are lathe cut contact lenses with spherical or aspherical, anterior or posterior surfaces in tinted version. The posterior curve is selected so as to properly fit an individual eye for orthokeratology for a temporary reduction of myopia and the anterior curve is selected to provide the necessary optical power. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

BOSTON XO contact lenses for orthokeratology are made from a fluoro silicone acrylate polymer, hexafocon A, with water content of less than 1% percent. The tinted lens contains D&C Green #6 for blue, ice blue lenses; D&C #6 Green and C.I. Solvent Yellow #18 for green lenses, D&C Violet #2 for violet lenses, D&C Red #17 for red lenses and C.I. Solvent Yellow #18 for yellow lenses. BOSTON XO contact lenses for orthokeratology are to be worn for daily wear only and should not be worn overnight.

LENS PARAMETERS AVAILABLE:

Chord Diameter Approx 6.5 to 11.5

Center Thickness for

Low Minus Lens: 0.10 to 0.30 mm
for Plus Lens: 0.20 to 0.70 mm

Base Curve 6.5 to 11.0 mm
Secondary Curves 0.10 to 2.00 mm

Flatter or steeper than
Base Curve

Peripheral Curves 0.10 to 2.0 mm

Flatter or steeper than
Base Curve

Powers -10.00 to +3.00 Dioptors

Aspheric Lens Eccentricity -1.5 to 1.5
(Oblate, Prolate or Tangent Conic)

The physical properties of BOSTON XO are:

Refractive Index 1.415

Light Transmission*

Tint	Transmittance
Blue	86%
Ice Blue	90%
Violet	87%
Green	90%
Red	94%
Yellow	97%

*Average CIE Luminous & Transmittance
(381 nm - 780 nm)

(lens center thickness = 0.65mm)

Wetting Angle 49°

(Contact Receding Angle)

Specific Gravity 1.27

Hardness (Rockwell) 112

Water Content <1 %

Oxygen Permeability 140** (100***)

** gas to gas method

***polarographic method (ISO/Fatt)

ACTIONS:

BOSTON XO contact lenses for orthokeratology produce a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye, and if the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and compensate for myopia. Contact lenses rest directly on the corneal tear layer and can influence the corneal shape. Regular RGP contact lenses are designed to cause little or no effect on the shape of the cornea, but BOSTON XO contact lenses for orthokeratology are designed to flatten the shape of the cornea by applying slight pressure to the center of the cornea. If the central cornea is flattened, this reduces the focusing power of the eye, and if the amount of corneal flattening is sufficient, it is possible to bring the eye into correct focus and compensate for myopia. After the contact lens is removed, the cornea generally retains its altered shape for part or all of the remainder of the day. A Myopic Reduction Maintenance Lens, also referred to as a Retainer Lens (see Wearing Schedule Section) should be worn each day to maintain the corneal flattening or the myopia will revert back to the pretreatment level.

INDICATIONS (USES):

The BOSTON XO (hexafocon A) RGP Contact Lens for orthokeratology is 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. The lens may be disinfected using a chemical disinfection

system only.

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

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE BOSTON XO Contact Lenses when any of the following conditions exist:

- Acute and subacute inflammations or infection of the anterior segment of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva or eyelids.
- Severe insufficiency of tears (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may affect the eye or be exacerbated by wearing RGP contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing RGP contact lenses or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for your contact lenses.
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated.

WARNINGS:

Caution: BOSTON XO contact lenses for orthokeratology are shipped to the practitioner non-sterile. Clean and condition lenses prior to use.

Incorrect use of contact lenses and lens care products can 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 contact lenses and lens care products. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, immediately remove your lenses and do not wear them until you have been examined by your eye care practitioner. All contact lens wearers should see their eye care practitioner according to the schedule given to them.

BOSTON XO contact lenses for orthokeratology are to be worn on a daily wear basis only. Do not wear your lenses while sleeping, at the risk of serious adverse reactions such as corneal infections or ulcers.

Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

PRECAUTIONS:

Specific Precautions

- Clinical studies have demonstrated that contact lenses manufactured from the BOSTON XO (hexafocon A) rigid gas permeable lens materials are effective for their intended use.

However, the clinical studies may not have included all design configurations or lens parameters that are presently available in the materials. Consequently, when selecting an appropriate lens design and parameter, the eye care practitioner should consider all factors that affect lens performance and ocular health. The potential impact of these factors should be weighed against the patient's needs; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored.

- 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 types of solutions are safe for use with all lenses. Use only recommended solutions with the contact lenses.
- Do not heat the wetting/soaking solution and lenses.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts of the contact lens solutions used.
- Use only a chemical lens care system. Use of a heat (thermal) lens care system can cause damage by warping BOSTON XO 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).

Handling Precautions

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Be certain that your fingers or hands are free of foreign material before touching your contact lenses as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the patient information 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 such tools are specifically indicated for that use. Pour your lens into your hand.
- Do not touch the lens with your fingernails.
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

Lens Wearing Precautions

- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens in the patient information booklet. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, you should immediately consult your eye care practitioner.
- Never wear your contact lenses beyond the period recommended by your eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products such as sprays are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rins-

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ing solution and allow to air dry.

- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care practitioner.

Some Topics to Discuss with the Eye Care Practitioner

- Ask your eye care practitioner about wearing your lenses during sporting activities.
- Always contact your eye care practitioner before using any medicine in your eyes.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.

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 not wear contact lenses.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO): Patients 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.
- 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).

If you notice any of the above: **IMMEDIATELY REMOVE YOUR LENSES.** If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, **DO NOT** put the lens back on your eye. Place the lens in the storage case and contact your eye care practitioner. If the lens has dirt, 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. 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, or iritis may be present. You should be instructed to keep the lens off the

eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

CLINICAL STUDY RESULTS:*

A total of 138 eyes were enrolled in the clinical study with 110 eyes completing a minimum of 3 months of contact lens wear. Of the completed eyes, a total of 106 eyes showed some reduction in myopic refractive error during the 3-month time period that the RGP contact lenses for orthokeratology were worn. The average reduction was 1.69 diopters with a range from 0.25 to 4.25 diopters.

The average amount of myopia that can be expected to be corrected is shown in the following table. These values are only averages and some patients can be expected to achieve more or less than these averages.

AVERAGE REDUCTION IN MYOPIA (Diopters)

INITIAL Myopia	REDUCTION Myopia
-1.00	0.80
-2.00	1.50
-3.00	2.00
-4.00	2.40

The amount of myopia reduced varied between patients and could not be predicted prior to treatment. There was an insignificant difference between the patients who wore contact lenses prior to the study and those with no previous contact lens experience.

RGP contact lenses for orthokeratology provided a temporary full reduction in some patients with up to 3.00 diopters of myopia. For patients with greater than 3.00 diopters of myopia, only a partial reduction of myopia can be expected. The percentage of patients that can be expected to achieve full or partial temporary refractive reduction is shown in the following table:

PERCENT OF EYES THAT ACHIEVED FULL OR PARTIAL TEMPORARY REDUCTION OF MYOPIA

INITIAL MYOPIA	FULL TEMP. REDUCTION	UP TO 0.50 D UNDER FULL REDUCTION	FINAL V.A. 20/20 OR BETTER	FINAL V.A. 20/40 OR BETTER
<1.00 D	52%	84%	78%	100%
-1.25 TO -2.00 D	36%	55%	74%	96%
-2.25 TO -3.00 D	18%	35%	48%	72%
-3.25 TO -4.00 D	4%	13%	16%	64%

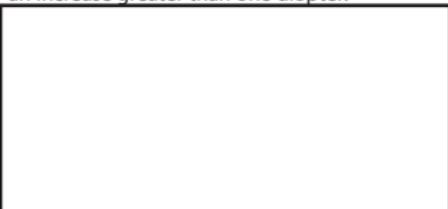
For the 110 eyes that completed this study, the initial visual acuity by best refraction was 20/20 or better for 104 eyes and 20/40 or better for all 110 eyes. At the final visit, visual acuity with contact lenses was equal to or better than 20/20 for 99 eyes, 20/40 for 109 eyes and one eye had a visual acuity of 20/70. Nine eyes had a one-line drop in visual acuity for contact lens-

es compared to best refraction, one eye had a two-line drop and three eyes had a three-line drop. In each case, the reduced visual acuity was attributed to residual astigmatism when wearing contact lenses.

The percentage of eyes that achieved uncorrected visual acuity of 20/20 or better and 20/40 or better in relation to the initial myopia is given in the above table. A total of 43 (39%) eyes achieved a visual acuity of 20/20 or better and 78 (71 %) eyes achieved 20/40 or better.

EFFECTS ON ASTIGMATISM

Either increases or decreases in astigmatism may occur following orthokeratology. Of the 110 eyes (55 patients) which completed the three month clinical, 8% showed no change in corneal astigmatism, 32% showed a decrease less than one diopter, while 41% showed an increase less than one diopter and 16% showed an increase greater than one diopter.



WEARING TIME

In the study, the average wearing time required for patients who wore RGP contact lenses for orthokeratology for various time periods was as follows:

One week	7.7 hours/day
Two weeks	7.8 hours/day
One month	8.0 hours/day
Three months	8.4 hours/day

There was considerable variability, however, as many patients required several hours more or less than the averages as shown for the three month time period as follows:

Daily Wear Time Worn	Percent of patients
0 to 4 hours	25.5%
4.1 to 8 hours	21.8%
8.1 to 12 hours	23.7%
12.1 to 16 hours	27.2%

*Data based on CONTEX (siflufocan A) 3-month Clinical Study.

FITTING:

Conventional methods of fitting rigid contact lenses for orthokeratology DO NOT APPLY to the BOSTON XO contact lenses for orthokeratology. For a description of fitting techniques, refer to the Fitting Guide for BOSTON XO contact lenses for orthokeratology, copies of which are available from:

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WEARING SCHEDULE:

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to follow the wearing schedule recommended by the eye care practitioner regardless of how comfortable the lenses feel.

The following schedule depends upon the professional judgment of the eye care practitioner and should be modified according to the response to the initial lenses.

Daily Wear Maximum wearing time:	Wearing Time (Hours)
Day 1	3
2	6
3	7
4	8
5	9
6	10
7	15
8 and after	All hours awake

Patients should be advised NOT TO SLEEP while wearing BOSTON XO contact lenses for orthokeratology. Studies have not been conducted to show that the BOSTON XO rigid gas

permeable contact lens is safe to wear during sleep. There is a tendency for some patients to overwear the lenses initially. It is important to remind patients to adhere to the maximum wearing schedule above. In order to maintain the orthokeratology effect of myopia reduction, lens wear should be continued on a wearing schedule determined by the eye care practitioner. Refer to the Professional Fitting and Information Guide or the Patient Information Booklet, Part 1, for information on Myopic Reduction Maintenance Lens or Retainer Lens wear.

LENS CARE DIRECTIONS:

The lens care products listed below are recommended by Bausch & Lomb for use with your BOSTON XO orthokeratology contact lenses.

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

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The directions from the package inserts from these lens care products should be followed. Failure to adhere to these procedures may result in the development of serious ocular complications. You should not switch from one care system to another unless your eye care practitioner has determined that it is appropriate. Do not mix or alternate the disinfection and storage systems unless so indicated on the product label.

Always wash and rinse your hands thoroughly before handling your contact lenses.

BOSTON XO contact lenses for orthokeratology must be both cleaned, rinsed and disinfected each time you remove them. One procedure does not replace the other. Cleaning is neces-

sary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs. To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

Clean and rinse as directed in the solution labeling. Some solutions may have more than one function which will be indicated on the label. Clean one lens first (the recommended procedure is to always clean the same lens first to avoid mix-ups). Rinse the lens thoroughly to remove the cleaning solution. Place the lens into the correct storage chamber and fill the chamber with the recommended disinfection solution as recommended by your eye care practitioner.

Tightly close the top of each chamber of the lens storage case.

To disinfect your lenses, leave them in the solution for at least the period of time indicated on the solution label. Leave the lenses in the unopened storage case until you are ready to put them in your eye.

LENS CASE CLEANING AND MAINTENANCE:

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

ENZYME CLEANING:

Your eye care practitioner may recommend enzyme cleaning. Enzyme cleaning does not replace routine cleaning and disinfecting. You should carefully follow the instructions in the enzymatic cleaning labeling.

EMERGENCIES:

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 and then remove lenses promptly.

CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED:

Each lens is supplied non-sterile in an individual plastic case. The case, packing slip or invoice is marked with the base curve, dioptric power, diameter, secondary curve, center thickness, color and lot number.

REPORTING OF ADVERSE REACTIONS:

All adverse reactions should be reported immediately to the manufacturer. Telephone 800-333-4730.

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