PATIENT INFORMATION

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

Daily Wear

Part 1
For Potential Users

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

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GLOSSARY

Adnexa:	Tissues near the eye.
Adverse effects:	Undesirable effects.
Aphakia:	Eye that does not have a lens structure.
Astigmatism:	Eye condition in which one or more surfaces of the cornea or lens has a shape that is not round but more like that of a spoon.
Contact Lens Sticking:	Lack of movement of a contact lens on the cornea.
Cornea:	The clear, bubble-like structure on the front of the eye, where light first enters the eye.
Corneal abrasion:	Loss of cells on the corneal surface due to mechanical trauma.
Corneal edema:	Accumulation of fluid in the cornea.
Corneal hypoesthesia:	Partial loss of sensitivity to touch in the cornea.
Corneal staining:	Bright areas on the cornea where dye collects and which indicates an abrasion or other disturbance of the cornea.
Corneal ulcer:	Small area of tissue loss in the cornea.
Disinfection:	Destruction of bacteria and viruses but not some spores.
Diopter:	Unit of power for glasses or contact lenses.
Enzyming contact lenses:	Placing contact lenses in a solution that contains an enzyme that dissolves proteins on the surface of the lens.
Hypoesthesia:	Reduced corneal sensitivity to touch.
Iritis:	Infection of the iris or colored portion of the eye.
Lacrimal secretion:	Tearing.
Myopia:	Medical term for nearsightedness.

Myopic Reduction Maintenance Lens:	A modification of the orthokeratology contact lens design in which the central portion of the lens applies just enough pressure to the cornea to maintain the corneal flattening achieved but with no additional corneal flattening.
Neovascularization:	New vessel growth in the cornea.
Orthokeratology:	Contact lens fitting procedure that temporarily reduces nearsightedness after contact lenses have been removed.
Refract:	Bending of light in order to make it focus.
Refractive anomalies:	Eye conditions leading to blurred vision including nearsightedness, farsightedness and astigmatism.
Retainer Lens:	Another name for the Myopic Reduction Maintenance Lens.
Retina:	Structure at the back of the eye that receives the light image.
Rewetting contact lenses:	Placing a solution in the eye while contact lenses are worn that acts as an artificial tear to wet the lens.
Sticking lens:	Lens on the cornea that does not move.

INTRODUCTION

The information in this booklet is to help you decide whether or not to be fitted with the BOSTON XO contact lenses for orthokeratology. Orthokeratology is a contact lens fitting procedure that temporarily reduces nearsightedness (known by the medical name of myopia) after contact lenses have been removed. By temporary it is meant that the contact lenses are worn for a portion of the day and then removed, whereupon the nearsightedness remains reduced for all or part of the remainder of the day. The exact time period over which the myopia remains reduced varies with each patient. Generally, BOSTON XO contact lenses for orthokeratology should be worn for part of each day for the orthokeratology effect to continue.

HOW THE EYE FUNCTIONS

The eye is very much like a camera and must be in good focus to see objects clearly. The focusing power of the eye comes from two eye structures, the cornea and the lens [(Figure 1)]. The cornea is the clear, bubble-like structure on the front of the eye, where light first enters the eye. It provides about two thirds of the eye's focusing power, and the lens inside the eye provides the other third. In a normal eye light focus at the retina, at the back of the eye, which acts like the film in a camera. Some eyes focus, or refract, the light too much, so that the images of distant objects are formed in front of the retina, and the image on the retina is blurred, producing myopia [(Figure 2)].

Myopia usually starts in childhood and gets progressively worse through adolescence. It normally stops increasing by the late teens, but it can sometimes continue to get worse into the mid-twenties.

HOW BOSTON XO CONTACT LENSES FOR ORTHOKERATOLOGY FUNCTION

BOSTON XO contact lenses for orthokeratology produce a temporary reduction of nearsightedness by changing the shape (flattening) of the cornea, which is elastic in nature. Contact lenses rest directly on the cornea, separated only by a layer of tears, and can influence the corneal shape. Regular contact lenses are designed to nearly match the shape of the cornea and thereby cause little or no flattening effect, but BOSTON XO contact lenses for orthokeratology are specifically designed not to match the shape of the cornea in order to apply slight pressure to the center of the cornea [(Figure 3)], in a design known as reverse geometry. Pressure is produced when the lens is less curved than the cornea, which places more of the lens weight on the center of the cornea. If the 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 [(Figure 4)]. After the lens is removed, the cornea generally retains its altered shape for all or part of the remainder of the day.

Figure 1: Normal Eye

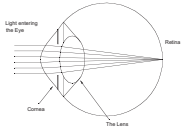


Figure 2: Nearsighted eye

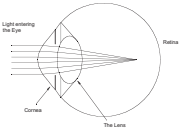


Figure 3: Eye Fitted With BOSTON XO contact lenses for orthokeratology.

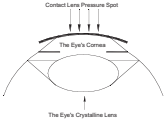
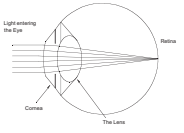


Figure 4: Nearsighted Eye After Orthokeratology



BOSTON XO contact lenses for orthokeratology are indicated for patients who desire to have time periods during the day in which they do not need to wear their contact lenses, but still be able to see clearly. This might include such activities as swimming and other sports. BOSTON XO contact lenses for orthokeratology may be indicated in occupations that require exposure to smoke, noxious gases or conditions of low humidity in which case contact lenses can be removed without interference with vision. Some patients are content to wear their contact lenses for normal activities during part of the day and remove them for evening activities.

ALTERNATIVE WAYS TO CORRECT NEARSIGHTEDNESS

Nearsightedness (myopia) can be corrected by any method that reduces the focusing power of the eye. The most common methods of reduction are by glasses or regular contact lenses. These represent a means of correcting myopia only during the time that the glasses or regular contact lenses are worn, with no lasting effect on the myopia. Other methods of correcting myopia involve various surgical procedures. These involve techniques to reshape the cornea so that it is flattened in a way that is similar to that produced by BOSTON XO contact lenses for orthokeratology, except that the surgical procedures are permanent.

CLINICAL STUDY DATA*

BOSTON XO contact lenses for orthokeratology may produce a temporary reduction of all or part of your myopia. The amount of reduction will depend on many factors, including the amount of your initial myopia, the elastic characteristics of your eye, and the way that your contact lens fits on your eye.

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 lenses 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

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 (siflufocon A) 3-month Clinical Study.

MAINTAINING EFFECTS OF BOSTON XO CONTACT LENSES

FOR ORTHOKERATOLOGY

MYOPIC REDUCTION MAINTENANCE LENS OR RETAINER LENS WEAR

The long-term wear of BOSTON XO contact lenses for orthokeratology does not eliminate the need to continue wearing contact lenses to produce the orthokeratology effect. After the cornea has been flattened by wearing BOSTON XO contact lenses for orthokeratology, new lenses are prescribed that are Myopic Reduction Maintenance Lenses also referred to as a Retainer Lenses. Retainer Lenses are a modification of the patient's BOSTON XO contact lens for orthokeratology design in which the central portion of the lens applies just enough pressure to the cornea to maintain the corneal flattening achieved but with no additional corneal flattening. The Retainer Lenses are generally worn for the same schedule as the BOSTON XO contact lenses for orthokeratology and should be worn each day to maintain the orthokeratology effect.

Studies have not been conducted to support the safety of wearing BOSTON XO contact lenses for orthokeratology for overnight or extended wear and the lenses should not be worn overnight.

RISK ANALYSIS

There is a small risk involved when any contact lens is worn. It is not expected that, when used as prescribed for daily wear, BOSTON XO contact lenses for orthokeratology will provide a risk that is greater than other rigid gas permeable contact lenses.

The two most common side effects that occur in rigid contact lens wearers are corneal edema and corneal staining. It is anticipated that these two side effects will also occur in some wearers of BOSTON XO contact lenses for orthokeratology. Other side effects that sometimes occur in all contact lens wearers are pain, redness, tearing, irritation, discharge, abrasion of

the eye or distortion of vision. These are usually temporary conditions if the contact lenses are removed promptly and professional care is obtained.

In rare instances, there may occur permanent corneal scarring, decreased vision, infections of the eye, corneal ulcer, iritis, or neovascularization. The occurrence of these side effects should be minimized or completely eliminated if proper schedule of care is followed. You should remove your contact lenses if any abnormal signs are present. Never wear your contact lenses while in the presence of noxious substances. Be certain to return for all follow-up visits required by your eye care practitioner.

WEARING RESTRICTIONS AND INDICATIONS

INDICATIONS

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 3.00 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 YOUR BOSTON XO contact lenses for orthokeratology when any of the following conditions exist:

- Acute and subacute inflammations or infection of the anterior chamber 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) if not aphakic.
- Any systemic disease, which may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa which may be induced or exaggerated by wearing 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 BOSTON XO contact lenses for orthokeratology.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes become red or irritated.

WARNINGS:

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

Daily wear lenses are NOT indicated for overnight wear, and you should not wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions such as corneal infection or ulcers is increased when contact lenses are worn overnight.

Safety and effectiveness of this device when worn overnight in an orthokeratology fitting and maintenance program have not been established.

Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that you 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.

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

If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye you should immediately remove your lenses and promptly contact your eye care practitioner.

1400 N. Goodman Street
Rochester, New York 14609

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PATIENT INFORMATION

Boston XO®
(hexafocon A)

RIGID GAS PERMEABLE CONTACT LENSES FOR ORTHOKERATOLOGY

Daily Wear

Part 2

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

BAUSCH + LOMB
Boston®
Lenses & Materials

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

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PRECAUTIONS

Specific Precautions

Clinical studies have demonstrated that contact lenses manufactured from the Boston XO® (hexafocon A) rigid gas permeable lens materials are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in this material. Consequently, when selecting an appropriate lens design and parameter, the eye care practitioner should consider all factors that affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter. The potential impact of these factors should be weighed against your needs. Therefore, your continuing ocular health and lens performance on the eye should be carefully monitored by your prescribing eye care practitioner.

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

Solution Precautions

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions with the contact lenses.
- Do not heat the wetting/soaking solution or lenses.
- Always use **fresh, unexpired** lens care solutions.
- Always follow directions in the package inserts of the contact lens solutions used.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) lens care system can cause damage by warping Boston XO® (hexafocon A) contact lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Do not use tap water as a rinsing agent.
- Tap water, distilled water, or homemade saline should not be used as a substitute for any component in the lens care regimen since they have been associated with an *Acanthamoeba* keratitis infection.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored).

Handling Precautions

- Always wash and rinse your hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Be certain that your fingers or hands are free of foreign material before touching your contact lenses as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing, and wearing instructions in this booklet and those prescribed by your eye care practitioner.
- Always handle your lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. To remove the lens from the case, pour the solution containing the lens into the palm of your hand.
- Do not touch the lens with your fingernails.
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

Lens Wearing Precautions

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

Lens Case Precautions

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air-dry.
- Replace the lens case according to the directions given by your eye care practitioner or the labeling that came with your case.

Topics to Discuss with Your Eye Care Practitioner

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

Who Should Know That the Patient is Wearing Contact Lenses

- Inform your doctor (health care practitioner) about being a contact lens wearer.
- Always inform your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you do not wear contact lenses.

ADVERSE REACTIONS

You should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain.
- Comfort is less than when lens was first placed on eye.
- Abnormal feeling of something in the eye (foreign body, scratched area).
- 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, you should:

- **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. After reinsertion, if the problem continues, you should **immediately remove the contact lenses and consult your eye care practitioner.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, iritis, persistent stromal edema, or GPC (giant papillary conjunctivitis) may be present. You should **keep the lens off your eye and seek immediate professional identification** of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS AND LENS HANDLING

1. Preparing the Lens for Wearing

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

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

2. Handling the Lenses

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

3. Placing the Lens on the Eye

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

After thoroughly washing and rinsing your hands, and after proper cleaning and conditioning of the lens, follow these steps to insert the lens:

- Remove the lens from its storage compartment.
- Rinse the lens with fresh conditioning solution, if desired.
- Inspect the lens to be sure that it is clean, uniformly wet and free of debris.
- Rub several drops of conditioning solution over the lens surfaces.
- Place the lens on the top of the index finger of your dominant hand. Place the middle finger of the same hand close to the lower lash and hold down the lower lid.
- Use the forefinger or middle finger of your other hand to lift the upper lid and then place the lens on the eye. It is not necessary to press the lens against the eye.
- Gently release the lids and blink. The lens will center automatically. Always verify its proper position by checking your vision immediately after insertion.
- Use the same technique or reverse the hand when inserting the other lens.

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

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" section).
- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:
  a. Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
  b. The lens is on the wrong eye.

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eye care practitioner.

4. Centering the Lens

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens, follow the procedure below:

- Close your eyelids and gently massage the lens into place through the closed lids.

OR

- Gently push the off-centered lens onto the cornea while the eye is open using finger pressure on the upper or lower lid next to the edge of the lens.

5. Removing the Lens

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

a) A lens storage case

b) Lens care system

c) A clean towel

Always remove the same lens first.

- Wash, rinse, and dry your hands thoroughly.
- Work over a table with a clean towel. Do not remove lenses over a sink.
- There are two suggested methods of lens removal:

TWO-FINGER METHOD

a. Place a towel under your eye to catch the lens.

b. 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.

c. Press the lid margin inward and then together. The lens should be wedged out of your eye onto your hand or towel.

d. The lens may come out but remain on your eyelid or hand to be decentered onto the white part of your eye. If the latter occurs, re-center the lens onto your 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.

a. 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.)

b. Blink briskly. The lens will be pinched by the pressure of your eyelids and the lens will pop out onto the clean surface of the towel, or you may catch the lens in the palm of your hand.

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

- Remove the other lens by following the same procedure.
- Follow the required lens care procedures described under the heading, CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE, AND REWETTING/LUBRICATING).

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

For continued safe and comfortable wearing of your lenses, it is important that you **first clean and rinse, then disinfect** your lenses after each removal using the care regimen recommended by your eye care practitioner.

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

If you require only vision correction, but will not or cannot adhere to a recommended care regimen, or are unable to place and remove lenses or have someone available to place and remove them, you should not attempt to wear contact lenses.

When you first receive your lenses, be sure to practice putting on your lenses and removing them while you are in your eye care practitioner's office. At that time, you will be provided with a recommended cleaning and disinfection regimen, as well as instructions and warnings for lens care, handling, cleaning, and disinfection. Your eye care practitioner should instruct you about appropriate and adequate procedures and products for your use.

1. Soaking and Storing Your Lenses

Instructions for Use:

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

WARNING:

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

2. Rub and Rinse Time

Instructions for Use:

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

WARNING:

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

3. Lens Case Care

Instructions for Use:

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

WARNING:

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

4. Water Activity

Instructions 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. If your lenses have been submersed in water when swimming in pools, lakes, or oceans, you should discard them and replace them with a new pair. Ask your eye care practitioner for recommendations about wearing your lenses during any activity involving water.

5. Discard Date on Solution Bottle

Instructions for Use:

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

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

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use **fresh, unexpired** lens care solutions.
- Use the recommended system of lens care, which is chemical (not heat), and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling.**
- Always remove, clean, rinse, enzyme, and disinfect your lenses according to the schedule prescribed by your eye care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- Never rinse your lenses in water from the tap. There are two reasons for this:
  a. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
  b. You might lose the lens down the drain.
- **Clean** one lens first (always the same lens first to avoid mix-ups), **rinse** the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface. Follow the instructions provided in the cleaning solution labeling. Put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning and rinsing, **disinfect** the lenses using the system recommended by your eye care practitioner. Follow the instructions provided in the disinfection solution labeling.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately after disinfection, you should consult the labeling of the storage solution for information on lens storage.
- Always keep your lenses completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them again after a few weeks, ask your eye care practitioner for a recommendation on how to store your lenses.
- Boston XO® (hexafocon A) contact lenses for orthokeratology cannot be heat (thermally) disinfected.
- After removing your lenses from the lens case, empty and rinse the lens case with solution(s) recommended by the lens case manufacturer or the eye care practitioner, then allow the lens case to air-dry. When the case is used again, refill it with fresh storage solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.
- Your eye care practitioner may recommend a lubricating/rewetting solution for your use. **Lubricating/Rewetting** solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.

The lens care products listed in the following chart are recommended by Bausch + Lomb for use with your Boston XO® (hexafocon A) orthokeratology contact lenses.

Chemical Lens Care

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

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle and follow instructions.

7. Lens Deposits and Use of Enzymatic Cleaning Procedure

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

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

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

If the lens sticks (stops moving) or cannot be removed, you should apply 5 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 30 minutes, you should **IMMEDIATELY** consult your eye care practitioner.

9. Emergencies

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

WEARING AND APPOINTMENT SCHEDULES

Prescribed Wearing Schedule
Daily Wear

Maximum Wearing Time:

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

Appointment Schedule

Your appointments are on:

DAY	TIME	DATE

EYE CARE PRACTITIONER INFORMATION

Name _____

Address _____

Phone
Number _____

Emergency
Phone
Number _____

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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 Flatter or steeper than Base Curve	0.10 to 2.00 mm
Peripheral Curves Flatter or steeper than Base Curve	0.10 to 2.0 mm
Powers	-10.00 to +3.00 Dioptors
Aspheric Lens Eccentricity (Oblate, Prolate or Tangent Conic)	-1.5 to 1.5

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 (Contact Receding Angle)	49°
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 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 non-smokers.

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).

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 rinsing solution and allow to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care practitioner.

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 lenses 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 (siflufocon 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:

Bausch & Lomb Incorporated
1400 N. Goodman Street
Rochester, New York 14609

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:

Day	Wearing Time (Hours)
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 scheduled 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

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 necessary 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, dioptic 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.

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, New York 14609

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.

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