PACKAGE INSERT

BOSTON® XO (hexafocon A)

Spherical & Aspherical Contact Lenses for Myopia, Hyperopia & Keratoconus Bifocal/Multifocal Contact Lenses for Presbyopia and Toric Lenses to Correct Astigmatism in Not aphakic and Aphakic Persons

> Fluoro Silicone Acrylate Rigid 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 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 Contact Lenses (hexafocon A) material is used for the manufacturing of daily wear rigid gas permeable contact lenses. Boston XO Contact Lenses are wettable, non-hydrophilic rigid gas permeable contact lenses that are not surface treated and are made from siloxanyl fluoromethacrylate copolymer containing an utraviolet absorber. Boston XO Contact Lenses are available in ice blue and violet.

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
	D & C Yellow No. 18

The physical characteristics of the Boston XO material was designed to facilitate the fabrication of high-quality rigid gas permeable contact lenses in a wide range of lens designs.

Spherical Lens Design

Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	5.00 mm to 9.00 mm
Base Curve Hange	5.00 mm to 9.00 mm in 0.01 mm increment

Aspherical Lens Designs

(Some of these designs are patented; manufacture of these lenses in Boston XO (hexafocon A) materials are authorized to licensed labs only)

Power Range -20.00D to +20.00D in 0.25D increments 7.0 mm to 11.5 mm 6.00 mm to 9.20 mm in 0.01 mm increments

Bifocal/Multifocal Lens Designs

(Some of these designs are patented; manufacture of these lenses in Boston XO (hexafocon A) materials are authorized to licensed labs only)

Power Range -20.00D to +20.00D in 0.25D increments 8.5 mm to 11.5 mm Diameter 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
Diameter	in 0.25D increments 7.0 mm to 11.5 mm
Base Curve Range	6.80 mm to 9.50 mm in 0.01 mm increments
Toricity	Up to 9.00 Diopters

Keratoconus Lens Designs

Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	4.00 mm to 9.00 mm
Base Optic Zone	in 0.01 mm increments 5.00 mm to 9.00 mm in 0.01 mm increments

Physical/Optical Properties of Boston XO Contact Lenses:

Specific Gravity	1.27	,
Refractive Index	1.41	5
Light Absorbance (640 nm)	8.5	Blue
Light Absorbance (640 nm)	5.3	Ice Blue
Light Absorbance (585 nm)	5.3	Violet
Light Absorbance (640 nm)	4.9	Green
(absorbance units/inch)		

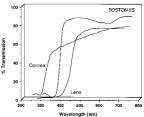
Light Transmittance* 92%
*Average %T (400-800nm)

Surface Character Hydrophobic Wetting Angle 49°

Water Content <1% Oxygen Permeability 140* (100**)

{x 10-11 (cm3 O2 • cm)/(cm2 • sec • mmHg) @ 35° C}

**polarographic method (ISO/Fatt)



Boston XO - 0.07 mm thick Boston XO 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 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.

^{*} gas to gas method

INDICATIONS (USES)

Boston XO Contact Lenses are indicated for daily wear for the correction of refractive ametropia (imyopia, hyperopia, astigmatism, presbyopia and keratoconus) in aphakic and not aphakic persons with non-diseased eyes. These contact lenses may be disinfected using a chemical disinfecting system only.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE Boston XO 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 evelids
- 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 Contact Lens materials.

- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes

WARNINGS

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

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

PRECAUTIONS

Practitioner Note: Boston XO 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:

Color	Center Thickness
Blue	>0.65 mm
Ice Blue	>0.65 mm
Violet	>0.65 mm
Green	>0.55 mm

- Special Precautions for Eye Care 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 eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.
- Patients who wear contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Aphakic patients should not be fitted with the Boston XO Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eye care practitioner's office, the patient should be able to properly remove lenses or should have someone else available who can remove the lenses for him or her.
- Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- The presence of the ultraviolet (UV) light absorber in the Boston XO Contact Lenses may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Fitting Guide for detailed instructions.)

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

- Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Do not heat the conditioning/storage solution and/or lenses. Keep them away from extreme heat.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.

- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp the Boston XO Contact Lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting larger
- 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, 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 eve care practitioner.
- Always wash and rinse hands before handling lenses.
 Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup.
 Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient instructions for the Boston XO Contact Lenses and in those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your eye care practitioner about wearing lenses during water activities and other sports.
- Inform your health care practitioner (doctor) that you wear contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. To remove the lens from the lens case, pour the solution containing the lens into the palm of your hand.
- . Do not touch the lens with fingernails.

- Always contact your eye care practitioner before using any medicine in the eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may require that 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 eve
- 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, do not put the lens back on the eye. Place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues,

immediately remove the lenses and consult the eye care practitioner. When any of the above problems occur, a serious

condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to **keep the lens off the eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING

Conventional methods of fitting contact lenses apply to Boston XO Contact Lenses. For a detailed description of the fitting techniques, refer to the Boston XO Professional Fitting and Information Guide, copies of which are available from:

Practitioner Marketing Representative Polymer Technology 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 eye care practitioner.

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

Boston® XO 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 lense	s continue to be well-tolerated.

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

LENS CARE DIRECTIONS

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

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

Basic Instructions:

Always wash, rinse, and dry hands before handling contact lenses.

- Always use fresh unexpired lens care solutions.
- Use the recommended system of lens care, chemical (not heat) and carefully follow instructions on solution labeling. Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling, or if advised by the eye care practitioner.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting

lenses. Do not put lenses in the mouth.

- Lenses should be cleaned, rinsed, and disinfected each time they are removed. Cleaning and rinsing are necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful derms.
- Always remove, clean, rinse, and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of an enzyme or a cleaning solution does not substitute for disinfection.

The lens care products listed below are recommended by Polymer Technology for use with the Boston XO Contact Lenses. Eye care practitioners may recommend alternate products that are appropriate for the patient's use with his or her lens(es).

LENS CARE TABLE Lens Care System

Product

Purpose	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 or Boston Simplicity® 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 eye care practitioner to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or the eye care practitioner. Follow the instructions provided in the disinfecting solution packaging.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye care practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.
- Eye care practitioners may recommend a lubricating/rewetting solution which can be used

to wet (lubricate) lenses while they are being worn to make them more comfortable.

- Eye care practitioners may recommend a weekly enzymatic cleaner which can be used to effectively remove protein deposits from Boston® XO Contact Lenses.
- Boston XO 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 eye care practitioner, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eye care 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 eye care 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 EYE CARE 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 and lot number. Additional parameters of add power, segment height, prism ballast and truncation may be included for bifocal/multifocal lenses.

REPORTING OF ADVERSE REACTIONS

All serious adverse reactions observed in patients wearing the Boston® XO Contact Lenses or adverse experiences with the lenses should be reported to:

Consumer Affairs Polymer Technology 1400 North Goodman Street Rochester, NY 14609 1-800-333-4730

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PATIENT INSTRUCTIONS

BOSTON® XO (hexafocon A)

Spherical & Aspherical Contact Lenses for Myopia, Hyperopia & Keratoconus Bifocal/Multifocal Contact Lenses for Presbyopia and Toric Lenses to Correct Astigmatism in Not aphakic and Aphakic Persons

> Fluoro Silicone Acrylate Rigid Gas Permeable Contact Lenses For Daily Wear

> > CAUTION:

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

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INTRODUCTION

Your eye care practitioner has fit you with contact lenses known as Boston® XO. Boston XO spherical, toric and bifocal/multifocal lenses are manufactured from Boston XO contact lens material. It is essential that you strictly follow the recommended handling, cleaning and storage procedures. Failure to do so may eventually impair the performance of your lenses.

WEARING RESTRICTIONS AND INDICATIONS

Boston XO Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism, presbyopia and keratoconus) in aphakic and not aphakic persons with nondiseased eyes. The lens may be disinfected using a chemical disinfection (not heat) system only.

Boston XO Contact Lenses described in this booklet should be removed daily from your eyes for routine cleaning and disinfecting as prescribed by your eye care practitioner. Do NOT WEAR YOUR Boston XO CONTACT LENSES WHILE SLEEPING.

CONTRAINDICATIONS (REASONS NOT TO USE)

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

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality, other than keratoconus, that affects the cornea, conjunctiva, or evelids
- 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 contact lens material
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eves

WARNINGS

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

PRECAUTIONS

- You should carefully adhere to the following care regimen and safety precautions:
- Patients may experience a reduction in visibility while wearing these lenses in conditions of low illumination for the following color and center thickness:

Color	Center Thickness
Blue	>0.65 mm
Ice Blue	>0.65 mm
Violet	>0.65 mm
Green	>0.55 mm

- Before leaving the eye care practitioner's office, you should be able to properly remove lenses or should have someone else available who can remove the lenses for you.
- You should remove your lenses immediately if your eyes become red or irritated.
- Different solutions often cannot be used together, and not all solutions are safe for use with all lenses.
 Use only recommended solutions.
- Do not heat the wetting/soaking solution and lenses. Keep them away from extreme heat.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package insert for the use of contact lens solutions.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp Boston® XO Contact Lenses
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, they must first be cleaned, rinsed with water and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfected overnight prior to insertion.
- if the lens sticks (stops moving) on the eye, 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, immediately consult your eye care practitioner.
- Always wash and rinse hands before handling lenses.
 Do not get cosmetics, lotions, soaps, creams deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup.
 Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions that follow for the Boston XO Contact Lenses and those provided by your eye care practitioner.

- Never wear lenses beyond the period recommended by your eye care practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your eye care practitioner about wearing lenses during water activities and other sports.
- Inform your health care practitioner (doctor) that you wear contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. To remove the lens from the case, pour the solution containing the lens into the palm of your hand.
- Do not touch the lens with fingernails.
- Always contact your eye care practitioner before using any medicine in the eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Follow your eye care practitioner's instruction as to a recommended follow-up schedule.

ADVERSE EFFECTS

The following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eve 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 eves
- Unusual eye secretions
- Redness of the eyes
- · Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- · Sensitivity to light (photophobia)
- · Dry eyes

If you notice any of the above:

Immediately remove lenses.

• If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact your eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, **immediately**

remove the lenses and consult your eye care practitioner.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You should keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS FOR LENS HANDLING

1. Preparing the Lens for Wearing

- It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:
- Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle the lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.

Start off correctly by getting into the habit of always using proper hygiene procedures so that they become automatic.

2. Handling the Lenses

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

3. Placing the Lens on the Eve

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:

- \bullet The lens is not centered on the eye (see "Centering the Lens," next in this booklet).
- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:

- a. Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
- b. The lens is on the wrong eve.

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

4. Centering the Lens

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

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

OR

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

5. Removing the Lens

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

1) A lens storage case.

2) Two Bottle Care System

Boston Advance® Cleaner or Boston® Cleaner. AND Boston Advance® Comfort Formula Conditioning Solution or Boston® Conditioning Solution.

OR One Bottle Care System

Boston SimplUS™ Multi-Action Solution (Removes Protein, Cleans, Disinfects, Conditions & Cushions) or Boston Simplicity® Multi-Action Solution (Clean, Condition, Disinfect, Rinse & Cushion)

3) A clean towel.

Always remove the same lens first.

- a. Wash, rinse, and dry your hands thoroughly.
- b. There are two suggested methods of lens removal:

TWO-FINGER METHOD

- 1) Place a towel under your eye to catch the lens.
- 2) Place the tip of the forefinger of one hand on the middle of the upper lid margin and the forefinger of the other hand on the middle of the lower lid margin.
- Press the lid margin inward and then together. The lens should be wedged out of your eye onto your hand or towel.
- 4) The lens may come out but remain on your eyelid or hand or be decentered onto the white part of your eye. If the latter occurs, recenter 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.

 Place your index finger at the outer junction of your upper and lower lids, stretch the skin outward and slightly upward. (Do not allow your lid to slide over the lens.)

- 2) Blink briskly. The lens will be pinched by the pressure of your eyelids and the lens will pop out onto the clean surface of the towel, or you may catch the lens in the palm of your hand.
- c. Remove the other lens by following the same procedure.
- d. Follow the required lens care procedures described under the heading, CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, STORAGE AND REWETTING/LURRICATING)

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

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

1. Basic Instructions

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 which may have accumulated during wear. The ideal time to clean your lenses is immediately after removing them. Disinfecting is necessary to destroy harmful germs.

You should adhere to the recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS section above

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

When you first get your lenses, be sure you can place the lenses on your eyes and remove 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 and instructions and warnings for lens care, handling, cleaning, and disinfecting. Your eye care practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of the Patient Instructions for the Boston® XO Contact Lenses.

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 (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 your eye care practitioner.
- Always remove, clean, rinse and disinfect your lenses according to the schedule prescribed by your eye carp 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.
- The lens care products listed below are recommended by Polymer Technology for use with your Boston XO Contact Lenses. Your eye care practitioner may recommend alternate products that are appropriate for you to use with your Boston XO Contact Lenses.

LENS CARE TABLE

Product Lens Care System

Purpose Chemical (Not Heat)

Clean Boston Advance® Cleaner or Boston® Cleaner

Disinfect Boston Advance® Comfort

Boston Advance® Comfort Formula Conditioning Solution or Boston® Conditioning Solution

Store Boston Advance® Comfort Formula Conditioning Solution or Boston Conditioning Solution

Multi-Action Boston SimplUS™
(Clean, Condition,
Multi-Action Solution or
Disinfect, Rinse
and Cushion) Multi-Action Solution
Lubricate/Rewet Boston® Rewetting Drops

Weekly Boston® One Step
Enzymatic Liquid Enzymatic Cleaner

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) and rinse the lens thoroughly as recommended by your eye care practitioner to remove the cleaning solution, mucus, and film from the lens surface. Follow the instructions provided in the cleaning solution labeling. Put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the above recommended system by your eye care practitioner and/or the manufacturer. Follow the instructions provided in the disinfection solution labeling.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, you should consult the Package Insert or your eye care practitioner

for information on storage of your lenses.

- Always keep your lenses completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them again after a few weeks, ask your eye care practitioner for a recommendation on how to store your lenses.
- Boston XO Contact Lenses **cannot** be heat (thermally) disinfected.
- After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case

manufacturer or the eye care practitioner; then allow the lens case to air dry. When the case is used again, refill it with fresh storage solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

- Your eye care practitioner may recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.
- Your eye care practitioner may recommend a weekly enzymatic cleaner which can be used to effectively remove protein deposits from your Boston® XO Contact Lenses.

2. Care for a Sticking (Nonmoving) Lens

If the lens sticks (stops moving/cannot be removed), apply one to three drops of a recommended lubricating or rewetting solution directly to your eye and wait until the lens begins to move freely on the eye before removing it. If nonmovement of the lens continues after 5 minutes, you should immediately consult your eye care practitioner.

3. 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 eye care practitioner, and allowed to air dry after each use. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eye care practitioner.

4. Emergencies

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

INSTRUCTIONS FOR THE MONOVISION WEARER

- · You should be aware that, as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in all gazes that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to monovision. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer is your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations which are not visually demanding. For example, be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers' license requirements with monovision correction.
- Some monovision lens wearers will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, discuss with your eye care practitioner whether

you should have additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance vision is required.

- If you require very sharp near vision during prolonged close work, you may want to discuss with your eye care practitioner having additional contact lenses prescribed so that both eyes are corrected for near when sharp near vision is required.
- Some monovision lens wearers require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eye care practitioner.
- It is important that you follow your eye care practitioner's suggestions for adaptation to monovision contact lens therapy. You should

discuss any concerns that you may have during and after the adaptation period.

 The decision to be fit with a monovision correction is most appropriately left to the eye care practitioner in conjunction with the patient after carefully considering and discussing your needs.

CONSIDERATIONS FOR BIFOCAL/MULTIFOCAL LENSES

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

Your eye care practitioner may discuss the

following with you:

1. Adaptation

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

2. Driving at Night

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

3. Flare at Night

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

4. Visual Expectation

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

SAMPLE OF WEARING AND APPOINTMENT SCHEDULES

Wearing Schedule

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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.

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

APPOINTMENT SCHEDULE			
Minimum numbe	Minimum number of hours lenses to be worn at time of appointment:		
Your appointmen	ts are on:		
Month Ye	ear	Time	Date
PATIENT/EYE CAI	RE PRACTITIO	NER INFORM	MATION:
Eye care Practition	ner Informatio	on	
Practitioner Name	9:		
Practice Name:			
Practitioner Addre	ess:		
Practitioner Phon	e Number:		
Recommended Le	ens Care Regir	men:	
Cleaning S	Solution:		
			and difficulty upgring your larges aryou do not upgerstand the

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

PRACTITIONER IMMEDIATELY.

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