PROFESSIONAL FITTING AND INFORMATION GUIDE

Boston XO_2®
(hexafocon B)

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

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

Bifocal Contact Lenses for Presbyopia

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

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

Gas Permeable Contact Lenses for Daily Wear

BAUSCH + LOMB
Boston®
Lenses & Materials

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

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DESCRIPTION

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

Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses are treated to incorporate Hydra-PEG® Technology (HPT), which is a thin polyethylene glycol (PEG)-based polymer that is covalently (permanently) bonded to the surface of the contact lens and is designed to enhance the surface properties of the contact lens while retaining the mechanical properties of the underlying material.

When treated with HPT, the underlying material, hexafocon B, is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (dynamic contact receding angle) compared to untreated lenses. The resulting layer is hydrophilic and approximately 30 nm in thickness.

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

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

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

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

The tinted lenses contain the following color additives:

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

Specific Gravity	1.19
Refractive Index	1.424

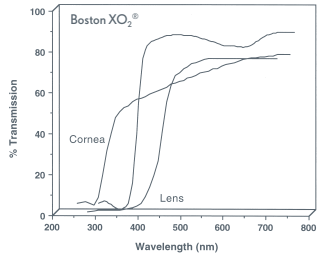
Light Transmittance*:

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

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

Surface Character	Hydrophobic
Wetting Angle	38°
Wetting Angle w/ Hydra-PEG	10°
Water Content	<1%
Oxygen Permeability:	
Edge Corrected	141**
Non-Edge Corrected	161**

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



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

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

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

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

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

ACTIONS

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

INDICATIONS

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

Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses are also indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes.
Note: To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

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

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

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

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

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

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

CONTRAINDICATIONS (REASONS NOT TO USE)

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

- Acute or subacute inflammation, or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality, other than irregular corneal conditions as described in the INDICATIONS section, that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if non-aphakic

- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa, that may be induced or exaggerated by wearing contact lenses or using contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for the Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses 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 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 the lenses** and promptly contact his or her eye care practitioner.

PRECAUTIONS

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

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

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

Special Precautions for Eye Care Practitioners:

- When wet shipped, Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses are packaged non-sterile in a preserved aqueous solution, either Boston SIMPLUS® Multi-Action Solution or Boston ADVANCE® Conditioning Solution. Boston SIMPLUS® Multi-Action Solution contains poloxamine, hydroxyalkyl phosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, glucam, and preserved with polyaminopropyl biguanide (0.0005%), chlorhexidine gluconate (0.003%). Boston ADVANCE® Conditioning Solution contains polyaminopropyl biguanide (0.0005%), chlorhexidine gluconate (0.003%), and edetate disodium (0.05%) as preservatives. If the patient has experienced a prior history of allergy to any of the ingredients in Boston SIMPLUS® Multi-Action Solution or Boston ADVANCE® Conditioning Solution, remove the lens from the solution and soak for 24 hours in unpreserved saline solution prior to cleaning, disinfecting, and dispensing.
- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.
- Patients who wear contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Aphakic patients should not be fitted with Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eye care practitioner's office, the patient should be able to properly remove lenses or should have someone else available who can remove the lenses for him or her.
- Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- The presence of the UV-absorber in the Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lens material may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the FITTING PROCEDURE 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_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses.
  - Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
  - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
  - Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored).
- If the lens sticks (stops moving) on the eye, follow the recommended directions on CARE FOR A STICKING (NON-MOVING) LENS. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eye care practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.

- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing, and wearing instructions in the Patient Information Booklet for Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses and those instructions provided by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Patients should be advised about wearing lenses during sporting and water related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including but not limited to, *Acanthamoeba* keratitis.
- The patient should be instructed to alert his or her doctor (health care professional) that the patient wears contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. To remove the lens from the case, pour the solution containing the lens into the palm of your hand.
- Do not touch the lens with fingernails.
- Always contact the eye care practitioner before using any medicine in the eyes.
- The patient should be instructed to inform his or her employer that the patient wears contact lenses. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when the lens was first placed on the eye
- Feeling of something in the eye, such as a foreign body or scratched area
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If you notice any of the above:

- **Immediately remove lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, **do not** put the lens back on the eye. Place the lens in the lens 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, 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 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. The Patient should **keep the lens off the eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

SELECTION OF PATIENTS

Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses are rigid gas permeable lenses for the daily wear patient who may require the correction of visual acuity for myopia, hyperopia, astigmatism, and presbyopia. Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses are suitable for patients who have never worn contact lenses, for current PMMA (polymethyl methacrylate) wearers, for patients wanting to upgrade their current rigid gas permeable lenses, as well as for some patients who have been unsuccessful with soft contact lenses.

FITTING PROCEDURE (ALL STEPS ALSO APPLY TO LENSES COATED WITH TANGIBLE® HYDRA-PEG®)

1. Pre-Fitting Examination

A pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for daily wear or extended wear contact lenses (consider patient hygiene and mental and physical state).
- Make ocular measurements for initial contact lens parameter selection.
- Collect and record baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination should include distance and reading refraction, keratometry, and slit lamp evaluation to rule out any contraindications to contact lens wear. Careful assessment of the cornea, lids, conjunctiva, and precorneal tear film establishes a baseline against which the eye care practitioner can compare any changes resulting from contact lens wear.

2. Initial Lens Diameter Selection

For minus lenses, an initial lens diameter of 9.6 mm is recommended. For plus lenses, an initial lens diameter of 9.2 mm is recommended. It is important that the optical zone of the lens covers the pupil adequately, even in dim illumination.

3. Initial Lens Base Curve Radius Selection

The initial base curve radius selection is primarily a function of the lens diameter selected and the amount of corneal astigmatism present:

Step One:
Measure central corneal curvature and identify the Flat K (lowest dioptric power).

Example:
K = 42.75/44.75 @ 90 Flat K = 42.75D (7.90 mm)

The "Flat K" is used as a reference point from which the Base Curve Radius is chosen.

Step Two:
Calculate the corneal astigmatism (difference between the Flat and Steep K).

In This Example:
K = 42.75/44.75 @ 90 Corneal Astigmatism = 2.00D

Step Three:
Calculate the Base Curve Radius by referring to the Corneal Astigmatism Factor Chart for a given lens diameter.

Example:
K = 42.75/44.75 @ 90 Flat K = 7.90 mm

Corneal Astigmatism = 2.00D
Lens Diameter = 9.6 mm
Initial Base Curve:

Flat K	42.75D 7.90 mm
+ Corneal Astigmatism Factor	0.25D flatter than Flat K
= Initial Base Curve	42.50D
Base Curve Radius	42.50D = 7.94 mm

Select 9.2 mm or 9.6 mm initial diameter. Choose base curve according to chart.		
Corneal Astigmatism Factors		
Corneal Astigmatism	**9.2 mm Diameter**	**9.6 mm Diameter**
0.00 to 0.50D	0.50D flatter	0.75D flatter
0.75 to 1.25D	0.25D flatter	0.50D flatter
1.50 to 2.00D	on Flat K	0.25D flatter
2.25 to 2.75D	0.25D steeper	on Flat K
3.00 to 3.50D	0.50D steeper	0.25D steeper
*This chart assumes an optical zone that is 1.4 mm to 1.6 mm smaller than the lens diameter		

4. Initial Lens Evaluation

A. Lens Positioning

Patient comfort is largely determined by lens positioning on the cornea. A slightly superior, lid-attachment positioning, is generally preferred to enhance comfort and encourage normal blinking patterns. Ideally, the upper edge of the lens should be located at or near the superior limbus and remain covered during each blink. A central lens positioning is acceptable but requires the lens periphery to be designed with minimal edge lift and edge contours that are rolled slightly inward, to reduce blink-related sensation. Inferior lens positioning, which interferes with normal blinking, promotes lens binding, and three and nine o'clock staining, should be avoided.

Note for fitting the hyperopic eye:
Single-cut plus lenses tend to position low. If the inferior decentration is modest, this design may be preferable, especially for smaller corneas. In many cases, lenticular-designed plus lenses offer better centration and more predictable blink-induced lens movement. Special attention must be directed to the edge design of interpalpebral lenticular lenses to ensure that they provide minimal lid sensation by being well-tapered and rolled slightly inward.

B. Fluorescein Pattern

Typically, the fluorescein pattern of the final lens should show some mild apical bearing ("feather" touch) or alignment and the absence of peripheral bearing over more than 180° of its circumference. Excessive apical pooling or bearing should be avoided. A moderate edge lift is necessary to permit the edge of the lens to slide over the corneal surface with minimal resistance.

The presence of the UV-absorber in the Boston XO_2® (hexafocon B) Contact Lenses may require equipment enhancement to visualize fluorescein patterns adequately. A simple, inexpensive approach is the use of an auxiliary yellow Kodak Wratten Filter #12 in conjunction with the cobalt blue filter of the biomicroscope.

Slit Lamp Application:

1. All customary light intensities and filter settings (cobalt blue) are left in place.
2. The Kodak Wratten Filter #12* (yellow) is secured on the patient side of the slit lamp microscope with a small piece of adhesive tape.

Burton Lamp Application:

1. Replace blue bulbs with ordinary white bulbs.
2. Place Kodak Wratten Filter #47* (blue) over white bulb area.
3. Place Kodak Wratten Filter #12 (yellow) over patient side of viewing lens.
4. Use system in usual manner.

Note: Use of the Wratten Filter will also enhance the view of non-UV rigid lenses and corneal fluorescein evaluation.

*The Wratten Filter #12 is available from Authorized Boston® Manufacturers in the following kit: #7503 Boston® Slit Lamp Filter Kit.

5. Initial Lens Power Selection

A. Empirical Fitting

Step One:
Follow the steps for Initial Lens Diameter Selection and Initial Lens Base Curve Radius Selection.

Step Two:
Employ the rules of steeper add minus (SAM) or flatter add plus (FAP) to determine lens power.

Example:
Spectacle Rx: -3.00-1.50 x 180
K Readings: 42.75/44.75 @ 90
Flat K = 42.75D (7.90 mm)
Corneal Astigmatism = 2.00D
Lens Diameter = 9.6 mm

Initial Base Curve:

Flat K =	42.75D	7.90 mm
+ Corneal Astigmatism Factor	0.25D flatter than Flat K	
= Initial Base Curve	42.50D	
Base Curve Radius	42.50D = 7.94 mm	

Since the base curve is 0.25D flatter than K, employ the FAP principle to determine contact lens power.

Base Curve:	42.50D 0.25 flatter than Flat K
Spherical Power of Spec Rx:	-3.00D
FAP Adjustment:	+(+0.25D)
Lens Power:	-2.75D

The lens in this example would be ordered as:

Base Curve:	42.50D
Power:	-2.75D
Diameter:	9.6 mm

B. Trial Fitting

Step One:
Perform a spherical refraction over the best fitting trial lens.

Step Two:
If the spherical power of the over-refraction is greater than 4.75D, correct for the vertex distance.

Example:
-5.00D at 12 mm = -4.75D at the cornea
+5.00D at 12 mm = +5.37D at the cornea

Step Three:
Combine the spherical over-refraction (corrected for vertex distance, if appropriate) with the power of the trial lens to obtain the final contact lens power ordered.

Example:		
	Trial lens	-3.00D
	Over-refraction	(+)+1.00D
	Power to Order	-2.00D

Vertex Conversion (12 mm distance) For minus powers reduce by amount shown. For plus powers increase by amount shown.				
±Spherical Over-refraction (D)	4.00 to 5.25	5.50 to 6.75	7.00 to 8.25	8.50 to 10.00
Corresponding Power Compensation (D)	0.25	0.50	0.75	1.00

6. Initial Lens Center Thickness Selection

The eye care practitioner should always specify center thickness as part of the complete prescription. The stability and flexural resistance of Boston XO_2® (hexafocon B) Contact Lens Material permit the use of a wide range of center thicknesses and designs.

For eyes with less than 1.25 diopters of corneal toricity consider the following standard thickness table:

Minus Lens Center Thickness	
Lens Power	**Recommended Thickness**
Plano	0.18
-1.00	0.17
-2.00	0.16
-3.00	0.15
-4.00	0.14
-5.00	0.13
-6.00	0.13
-7.00	0.13
-8.00	0.13

In cases where corneal toricity is 1.50 diopter or greater, consider adding 0.01 mm of thickness per diopter of cylinder to the center thickness table to control blink-induced flexure.

7. Remaining Lens Parameter Selection

The final prescription should be provided to the Authorized Boston® Manufacturer in a format which includes:

- base curve
- diameter
- power
- center thickness
- optic zone
- peripheral curves

By specifying the complete design, practitioner success and patient satisfaction are increased. **Your Authorized Boston® Manufacturer may also offer suggestions regarding lens design.**

Select remaining lens parameters: optical zone & peripheral (edge) design.			
Specify 8.0 mm to 8.2 mm optic zone Instruct manufacturer to blend to finished size			
Specify peripheral curve design as follows:			
for 9.2 mm diameter		**for 9.4 mm to 9.6 mm diameter**	
Peripheral Curves		**Peripheral Curves**	
	1st	**2nd**	**1st**	**2nd**
Width	0.3 mm	0.3 mm	**Width**	0.3 mm	0.3 mm
Radius*	0.8 mm	2.3 mm	**Radius***	1.2 mm	2.8 mm
**flatter than B.C.*			**flatter than B.C.*		

8. Follow-Up Care

- Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, a conventional follow-up schedule for daily wear should be maintained.
- Prior to a follow-up examination, the contact lenses should be worn for at least 2 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
- With lenses in place on the eyes, evaluate fitting performance to assure that Criteria of a Well-Fitted Lens continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
- After the lens removal, conduct a thorough biomicroscopy examination.
  - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
  - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
  - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the Criteria of a Well-Fitted Lens are not satisfied during any follow-up examination, the patient should be refitted with a more appropriate lens.

CAUTION: Damage may result from improper modification techniques. Consult your Authorized Boston® Manufacturer or contact Bausch + Lomb for more detailed information.

WARNING: Do **not** use solvents such as alcohols, esters, ketones, or chlorinated hydrocarbons (including naphtha, lighter fluid, etc.) since they may damage the lens surface and increase the brittleness of the lens. Only use the solvent supplied by your lens laboratory and minimize solvent exposure time by rubbing a solvent-saturated cloth over the lens surfaces and quickly removing the solvent with a surfactant. Do not soak the lenses in the solvent.

REMOVAL OF SURFACE DEPOSITS

Deposits are easily removed from the surfaces of Boston XO_2® (hexafocon B) Contact Lenses. These deposits are best identified by inspecting the cleaned and dried lens with a slit lamp in a dark room using a medium-width illuminating beam. Surface deposits should be gently removed with Boston® Professional Cleaning Polish, which is available in a kit form, with a polishing pad that permits practitioners to manually clean and polish their patient's rigid gas permeable lenses. The Boston® Professional Cleaning Polish and Manual Polishing Machine are available from Authorized Boston® Manufacturers. Do **NOT** use the Boston® Professional Cleaning Polish with Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses. These lenses should be returned to the Authorized Boston® Manufacturer.

Caution: Applying excessive and prolonged pressure to the lens during the polishing procedure may alter its surface optics. Do **NOT** polish the lenses coated with Tangible® Hydra-PEG®.

IN-OFFICE CARE OF TRIAL LENSES

Eye care practitioners should educate contact lens technicians concerning proper care of trial lenses. Prior to reusing in a diagnostic procedure or before dispensing to a patient, lenses should be surface cleaned and disinfected.

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

RECOMMENDED INITIAL WEARING SCHEDULE

Patients should be instructed to carefully follow the wearing schedule recommended by the eye care practitioner regardless of how comfortable the lenses feel.

Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses are indicated for **daily wear**.

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

CLINICAL ASSESSMENT

1. Criteria of a Well-Fitted Lens

Patient comfort is largely determined by lens positioning on the cornea. A slightly superior, lid-attachment positioning is generally preferred to enhance comfort and encourage normal blinking patterns. Ideally, the upper edge of the lens should be located at or near the superior limbus and remain covered during each blink. A central lens positioning is acceptable but requires the lens periphery to be designed with minimal edge lift and edge contours that are rolled slightly inward to reduce blink-related sensation. Inferior lens positioning, which interferes with normal blinking, promotes lens binding and three and nine o'clock staining, should be avoided.

Typically, the fluorescein pattern of the lens should show some mild apical bearing ("feather" touch) or alignment and the absence of peripheral bearing over more than 180° of its circumference. Excessive apical pooling or bearing should be avoided. A moderate edge lift is necessary to permit the edge of the lens to slide over the corneal surface with minimal resistance.

2. Optimizing Fitting Characteristics

Practitioner observations and interpretation of lens positioning, fluorescein patterns, and lens movement are essential to optimize the fitting process. The following chart summarizes common fitting relationships.

INITIAL LENS ASSESSMENT			
	Optimum	**Too Steep**	**Too Flat**
Fluorescein Pattern	Parallel to slight apical bearing, Moderate edge lift	Excessive apical pooling, Minimum edge lift	Excessive apical bearing, Excessive edge lift
Position	Centered to slightly superior	Inferior	Superior unstable
Movement	1 mm to 2 mm	Less than 1 mm	More than 2 mm
Comfort	Slight initial sensation	Initially comfortable	Uncomfortable
Disposition	Prescribe	Select flatter base curve or smaller diameter	Select steeper base curve or larger diameter

3. Problem Solving

Persistent excessive lens awareness: This problem may be due to: the use of incompatible care products; improper use of care products (i.e., lens cleaning just prior to insertion); three and nine o'clock staining; deposits on the concave lens surface; accumulation of mucus under the lens; poor edge design; incomplete blinking; or steeply fitted lenses.

Three and nine o'clock staining: If the lens position is low, it should be redesigned to achieve a higher position to avoid a false blink pattern. The lens periphery should be well tapered and its edge rolled slightly inward to minimize upper lid sensation and avoid incomplete reflex blinks. If the lens positions centrally, the diameter should be reduced, the periphery well tapered, and the edge rolled slightly inward. Complete blinking should be encouraged. ***Above all, be certain that the lens has not been fitted too steeply.***

Generalized corneal staining: In cases of diffuse staining not apparently related to back surface deposits on the lens, solution or preservative incompatibility should be ruled out.

Ocular redness without staining: This problem may be caused by some component of the care solutions, such as preservatives or the presence of pingueculae, infectious or allergic conjunctivitis, or inadequate lens lubrication, including excessive mucus accumulation as occurs in dry eyes.

Excessive development of lens deposits: This unusual problem may be related to: increased mucus production (i.e., GPC, keratitis sicca, chronic allergies, etc.). More frequent use of Boston® Rewetting Drops may be helpful in these cases. However, excessive deposition has been found to be most often related to inappropriately polished lens surfaces, which simulate an orange peel appearance only visible with magnification of 20X or greater. In many cases, for Boston XO_2® Contact Lenses without Tangible® Hydra-PEG®, deposits are easily removed by cleaning with original Boston® Cleaner, Boston ADVANCE® Cleaner, and/or Boston® ONE STEP Liquid Enzymatic Cleaner. However, in extreme cases, it may be necessary to lightly polish the lenses with Boston® Professional Cleaning Polish. **For Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses, DO NOT USE Boston® Cleaner, Boston ADVANCE® Cleaner, and/or Boston® ONE STEP Liquid Enzymatic Cleaner.** Do **NOT** polish lenses coated with Tangible® Hydra-PEG®. In the event that deposits cannot be removed by cleaning or polishing, the lens should be replaced.

Lens surface dry spots: The presence of discrete non-wetting areas on a new, recently modified, or polished lens is usually due to the persistence of hydrophobic products used during lens fabrication. These hydrophobic contaminants have a greater affinity for Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses polymers. Boston® Laboratory Lens Cleaner may be used to remove the dry spots for the Boston XO_2® Contact Lenses or the lenses should be returned to the Authorized Boston® Manufacturer for a special cleaning. Do **NOT** use the Boston® Laboratory Lens Cleaner with Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses. These lenses should be returned to the Authorized Boston® Manufacturer.

Other causes of loss of surface wettability include: surface contamination with cosmetics, hair spray, skin preparations; inadequate tear lubrication; incomplete blinking; the use of incompatible preserved care solutions; and dry lens storage.

Unstable vision: This problem may be due to excessive blink-induced lens flexure resulting from a steep fit. Unstable vision may also result from excessive blink-induced lens movement, an excessively small optical zone diameter, or surface dry spots.

Reduced contact lens-corrected vision: Reduced vision correction unrelated to changes in refractive error may be due to lens warpage, front surface deposits, or switched lenses.

Repeated lens breakage: Lens breakage problems may be due to careless handling or storage procedures (see Patient Information Booklet).

BIFOCAL/MULTIFOCAL CONTACT LENS FITTING PROCEDURE FOR THE PRESBYOPIC PATIENT

There are two categories of presbyopic lens designs discussed in this fitting guide, bifocal alternating vision designs, and multifocal simultaneous vision designs. Fitting information for each design is discussed in the following sections.

1. Pre-Fitting Examination

A pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for daily wear bifocal contact lenses (consider patient hygiene and mental and physical state),
- Make ocular measurements for initial contact lens parameter selection,
- Collect and record baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination should include distance and near refraction, keratometry, and slit lamp evaluation to rule out any contraindications to contact lens wear. Careful assessment of the cornea, lids, conjunctiva, and precorneal tear film establishes a baseline, against which the practitioner can compare any changes resulting from contact lens wear.

2. Alternating Vision Bifocal Designs

A. The first alternating vision design has a spherical base curve, a segment for distance correction, and a segment for near correction. For distance vision, the majority of the pupil is covered by the distance zone. For near vision, the majority of the pupil is covered by the near zone as the lens translates (moves upward) in downgaze. This design is prism ballasted to enhance stabilization.

Fitting Principles

1) Trial fitting is always recommended.
2) The base curve radius and distance powers are chosen using conventional techniques.
3) The near add power is based on the patient's refraction.
4) The diameter is chosen to place the segment line, which divides the distance, and near zones at or slightly below the inferior pupil margin.
5) With blinking the lens should move 1 mm to 2 mm. The segment line will raise above the inferior pupil margin but should drop quickly. If not, distance vision will be adversely affected.
6) Decreasing lens movement will generally improve distance vision. The following fitting adjustments will generally decrease movement:
   - Increase diameter
   - Steepen base curve
   - Increase prism ballasting
7) Increasing lens movement will generally improve near vision. The following fitting adjustments may increase movement:
   - Decrease diameter
   - Flatten base curve
   - Decrease prism ballasting

B. The second alternating vision lens design has a spherical base curve corresponding to the near point power and a steeper spherical curve segment corresponding to the distance power. For distance vision, the majority of the pupil is covered by the distance zone segment. For near vision, the majority of the pupil is covered by the near zone as the lens translates (moves upward) in downgaze. This design is prism ballasted and may have a small inferior truncation to enhance stabilization.

Fitting Principles

1) Trial fitting is always recommended.
2) The base curve radius is chosen using conventional techniques.
3) Determine the distance spherical power to obtain optimum visual acuity.
4) The diameter is chosen to correctly position the distance segment in front of the pupil in distance gaze. This can be visualized easily with fluorescein since the steeper distance segment pools with fluorescein.
5) The distance zone segment radius is calculated by multiplying the add requirement by two (2). This is added to the base curve (diopters).

   Example: Base Curve 43.00D
   Add +2.00 x 2 = 4.00D
   47.00D (distance zone curvature)

6) Calculate the power of the near zone (which corresponds to the base curve) by adding the distance power determined in step 3 to the add requirement.

   Example: -3.50D (distance power)
   (+) +2.00D (add power)
   -1.50D

7) Calculate the power of the distance zone segment by adding three (3) times the add power (as minus) to the near zone power.

   Example: 3 x - (2.00) -6.00 (3 x add power)
   (+) -1.50 (near zone)
   -7.50 (distance zone)

8) Specify the near and distance zone curvatures and powers.

   Example: 43.00/47.00 -1.50/-7.50
   43.00/-1.50
   47.00/-7.50

C. The third alternating vision design is an alternating vision bifocal lens with a spherical anterior surface and aspherical posterior surface. For distance vision, the majority of the pupil is covered by the near zone as the lens translates (moves upward) in downgaze. Prism ballasting and a small inferior truncation are incorporated to enhance orientational stability and translation in downgaze.

Fitting Principles

1) Trial fitting is always recommended.
2) Initial Base Curve Selection

   The initial base curve selection is primarily a function of the amount of corneal cylinder present. This bifocal lens with aspheric posterior surface will generally be fitted steeper (approximately 0.10 mm) than a similar diameter spherical lens.

   a) For Minus Lenses

      Select a base curve radius equal to the radius of the flattest keratometer reading for corneas with less than 1.00D of corneal toricity. For corneas with 1.00D or greater corneal toricity, select a base curve radius equal to the mean of the two keratometer readings.

      Example: K = 44.00/46.00 D
      Mean K = 45.00D = 7.50 mm
      Select 7.50 mm base curve trial lens
      (If conversion of diopters to millimeters results in a base curve parameter not available, select the next available steeper base curve.)

   b) For Plus Lenses

      Select a base curve radius equal to the corneal radius for spherical corneas. For toric corneas, select a base curve radius equal to the mean of the two (2) keratometer readings.

3) Place the lens on the eye and allow it to settle. (approximately 5 to 10 minutes).

3. Simultaneous Vision Multifocal Designs

A. The first simultaneous vision multifocal lens design has an aspheric back surface, which progressively adds plus power from center to edge. This power change is gradual. The distance and near power zones cover the pupil simultaneously during distance and near gaze. During distance viewing, the patient selectively attends to the distance correction. During near viewing, the patient selectively attends to the near correction.

Fitting Principles

1) Trial fitting is always recommended.
2) The base curve radius is chosen using conventional techniques. Due to the aspheric flattening of the lens back surface, the base curve chosen will be considerably steeper than standard spherical single vision rigid lenses. It is not unusual to select a base curve 2 to 4D steeper than the flattest K.

   The following formula can be used as a starting point:

   Flat K + add power + 1.00 D + 1/2 corneal astigmatism.

   Example: 42.00/44.00 + 2.00 add
   42.00 + 2.00 + 1 + 1 = 46.00

3) Centration is critical for this design. If proper exact centration cannot be obtained, do not fit this lens.
4) The distance power is chosen using conventional techniques. If more minus is required at distance than predicted, decentration might be the cause. When decentered, the pupil is covered by an intermediate (more plus) power zone. Decentration should be corrected rather than adjusting power.

B. The second simultaneous vision multifocal lens design has an aspheric front surface, which progressively adds plus power from center to edge. This power change is gradual. The distance and near power zones cover the pupil simultaneously during distance and near gaze.

During distance viewing, the patient selectively attends to the distance correction. During near viewing, the patient selectively attends to the near correction.

Fitting Principles

1) Trial fitting is always recommended.
2) The base curve radius is chosen using conventional techniques.
3) Centration is critical for this design. If proper exact centration cannot be obtained, do not fit this lens.
4) The distance power is chosen using conventional techniques. If more minus is required at distance than predicted, decentration might be the cause. When decentered, the pupil is covered by an intermediate (more plus) power zone. Decentration should be corrected rather than adjusting power.

C. The third simultaneous vision multifocal lens design lens employs a back surface annular design with a distinct distance and near zone. The distance and near power zones cover the pupil simultaneously during distance and near gaze. During distance viewing, the patient selectively attends to the distance correction. During near viewing, the patient selectively attends to the near correction.

Fitting Principles

1) Trial fitting is always recommended.
2) The base curve radius is chosen using conventional techniques.
3) Centration is critical for this design. If exact centration cannot be obtained, do not fit this lens.
4) The distance power is chosen using conventional techniques. If more minus is required at distance than predicted, decentration might be the cause. When decentered, the pupil is covered by an intermediate (more plus) power zone. Decentration should be corrected rather than adjusting power.

D. The fourth simultaneous vision multifocal lens design employs a front surface annular design with a distinct distance and near zone. The distance and near power zones cover the pupil simultaneously during distance and near gaze. During distance viewing, the patient selectively attends to the distance correction. During near viewing, the patient selectively attends to the near correction.

Fitting Principles

1) Trial fitting is always recommended.
2) The base curve radius is chosen using conventional techniques.
3) Centration is critical for this design. If proper exact centration cannot be obtained, do not fit this lens.
4) The distance power is chosen using conventional techniques. If more minus is required at distance than predicted, decentration might be the cause. When decentered, the pupil is covered by an intermediate (more plus) power zone. Decentration should be corrected rather than adjusting power.

4. Initial Lens Evaluation

A. Lens Positioning

Patient comfort is largely determined by lens position on the cornea. Generally, a well-fitted lens exhibits a central or slightly inferior/central position. Generally, an optimal aspherical fit will show a thin, even layer of tears centrally which extends to near the edge where a moderate amount of edge lift will be observed. This fluorescein pattern is characterized by the absence of a discernible intermediate bearing area which is commonly observed with conventional spherical designs.

B. Fluorescein Pattern

Excessive apical pooling or bearing should be avoided. A moderate edge lift is necessary to permit the edge of the lens to slide over the corneal surface with minimal resistance.

The presence of the UV-absorber in the Boston® lens may require equipment enhancement to visualize fluorescein patterns adequately. A simple, inexpensive approach is the use of an auxiliary yellow Kodak Wratten Filter #12 in conjunction with the cobalt blue filter of the biomicroscope.

Slit Lamp Application:

1. All customary light intensities and filter settings (cobalt blue) are left in place.
2. The Kodak Wratten Filter #12* (yellow) is secured on the patient side of the slit lamp microscope with a small piece of adhesive tape.

Burton Lamp Application:

1. Replace blue bulbs with ordinary white bulbs.
2. Place Kodak Wratten Filter #47* (blue) over white bulb area.
3. Place Kodak Wratten Filter #12 (yellow) over patient side of viewing lens.
4. Use system in usual manner.

Note: Use of the Wratten Filter will also enhance the view of non-UV rigid lenses and corneal fluorescein evaluation.

*The Wratten Filter #12 is available from Authorized Boston® Manufacturers in the following kit: #7503 Boston® Slit Lamp Filter Kit.

5. Determining Power and Dispensing the Lens

Once the appropriate base curve has been selected, over-refract to determine the appropriate distance dioptric power for the final lens order. Over-refractions of 4.00D or more should be corrected for vertex distance. The over-refraction should be added to the power of the trial lens to arrive at the final prescription.

Example:	Over-refraction	+0.50D
	Trial Lens	-3.00D
	Lens Power Ordered	-2.50D

Add power should be based on the spectacle add power required. Prior to dispensing the lens, clean the lens with an approved cleaner and store the lens wet in an approved wetting and soaking solution for at least four hours to ensure maximum patient comfort. Upon dispensing, evaluate the patient's lens using the same criteria previously described to evaluate the trial lens fitting.

6. Near Segment Positioning

A. Generally, in alternating vision designs the near segment line should be positioned slightly below the inferior margin of the pupil. This is achieved by varying the lens base curve/corneal fitting relationship and/or the segment height. Segment height is specified as either 0.5 mm or 1.0 mm below the geometric center of the lens, or as a segment height in mm from the bottom of the lens.

B. To bias toward better distance vision (decrease instability and improve acuity), less movement, lower post-blink segment positioning, and faster return times from post to pre-blink positions are helpful. The following may be helpful:

- Steepen Fit
- Lower Segment

C. To bias toward better near vision (increase acuity), more movement and higher post-blink segment positioning are useful. The following may be helpful:

- Flatten Fit
- Raise Segment

D. Lower segment positioning in conjunction with flatter fitting may represent the best compromise between distance and near visual performance.

E. Visual performance will improve with time as the patient learns to control the movement and positioning of the lens. The following patient instructions may be useful:

- Advise the patient that fluctuating vision at distance and near is possible, especially at first. Generally, blinking gently will improve distance vision.
- Strong blinking will improve near vision. When reading, the eyes, not the head, should turn downward.

7. Follow-Up Care

A. Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, a conventional follow-up schedule for daily wear should be maintained.

B. Prior to a follow-up examination, the contact lenses should be worn for at least 2 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.

C. With lenses in place on the eyes, evaluate fitting performance to assure that Criteria of a Well-Fitted Lens continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.

D. After the lens removal, instill sodium fluorescein into the eyes and conduct a thorough biomicroscopy examination.

1) The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.

2) The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.

3) Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the Criteria of a Well-Fitted Lens are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

CONSIDERATIONS FOR BIFOCAL/MULTIFOCAL LENSES

Presbyopic patients who are considering bifocal/multifocal contact lenses should be informed of the benefits as well as the problems they may encounter while adapting to bifocal/multifocal lens wear.

The following areas should be discussed with the patients.

A. Adaptation

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

B. Driving at Night

Patients wearing bifocal/multifocal contact lenses should experience night vision before actually driving while wearing their lenses.

C. Flare at Night

Patients wearing bifocal/multifocal contact lenses may experience flare at night. This may occur with certain lens designs (high segment positions or small distance fields). With time, patients adapt to this situation.

D. Visual Expectation

Patients wearing bifocal/multifocal contact lenses may experience visual acuities less than what could be achieved with bifocal spectacles.

MONOVISION FITTING GUIDELINES

1. Patient Selection

A. Monovision Needs Assessment

For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient may not be a good candidate for monovision with the Boston XO_2® Contact Lenses.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

1) Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

2) Driving automobiles (e.g., driving at night). Patients who cannot pass their state driver's license requirements with monovision correction should be advised not to drive with this correction or may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

A. Ocular Preference Determination Methods

Method 1 - Determine which eye is the "dominant eye." Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2 - Determine which eye will accept the added power with the least reduction in vision. Place the appropriate plus power trial spectacle lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the plus power trial lens over the right or left eye.

B. Refractive Error Method

For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic eye) for near.

C. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction, consider correcting the eye on that side for near.

Example:
A secretary who places copy to the left side of the desk may function best with the near lens on the left eye.

3. Special Fitting Considerations

Unilateral Lens Correction
There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

Example:
A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and no lens on the other eye.

A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left eye uncorrected for near.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

5. Trial Lens Fitting

A trial fitting can be performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and base curve selection described earlier in the guide.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place, observe the reaction to this mode of correction. Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again, assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these visual tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g., 12 point) at first and then graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mildly blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for only minutes or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process, the patient can be advised to use the lenses first in a comfortable familiar environment, such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to drive only during optimal driving conditions (e.g., sunny and dry). After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. Other Suggestions

The success of the monovision technique may be further improved by having your patient follow the suggestions below.

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when performing visual tasks.

Success in fitting monovision can be improved by the following suggestions.

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

Note: The decision to fit a patient with a monovision correction is most appropriately left to the eye care practitioner in conjunction with the patient after carefully considering the patient's needs. All patients should be supplied with a copy of the Patient Information Booklet.

IRREGULAR CORNEA FITTING GUIDELINES

1. Patient Selection Criteria

Boston XO_2® Contact Lenses are indicated for patients who require a rigid contact lens who have a demonstrated need for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or LASIK surgery, who desire a refractive correction with rigid gas permeable contact lenses and who do not have any of the contraindications for gas permeable contact lenses. Refer to CONTRAINDICATIONS (REASONS NOT TO USE).

Keratoconus is a non-inflammatory ocular condition in which the cornea progressively thins causing a cone-like bulge to develop. As the cornea steepens the anterior corneal surface (epithelium) becomes irregular resulting in visual impairment. This irregularity cannot be completely corrected with spectacles, instead a rigid gas permeable contact lens is used to become the new anterior refracting surface.

Pellucid Marginal Degeneration is characterized by non-inflammatory and progressive crescent shaped corneal thinning inferiorly, often with against-the-rule astigmatism and a steepening topography pattern.

2. Special Fitting Considerations

Boston XO_2® Contact Lenses for keratoconus, pellucid marginal degeneration, or post-penetrating keratoplasty (PRK)/LASIK are designed to be fitted so as to optically correct irregular astigmatism and thereby improve visual acuity. The lens designs and the manner in which the lens is fitted are intended to work together to accomplish this goal.

The keratoconus design utilizes smaller optic zone diameters, steeper base curves, spherical and/or aspherical periphery curves to closely approximate the unusual topography typical in patients with keratoconus. For example, keratoconus lens designs utilize small posterior optic zones and a series of peripheral curves to achieve this fitting relationship. These zone sizes may vary in lens diameters over 11.5 mm.

The Pellucid Marginal Degeneration design utilizes larger lens diameters, larger optic zone diameters, flatter base curves, and spherical and/or aspherical periphery curves to closely approximate the unusual topography typical in patients with the condition.

Boston XO$_2$® Contact Lenses for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery, may be fitted using a modification of the standard techniques for rigid gas permeable contact lenses.

A. Pre-Fitting Examination

Complete refraction and visual health examination should be performed.

Pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for Boston XO$_2$® Contact Lenses for keratoconus, pellucid marginal degeneration, irregular astigmatism, excessive dry eyes, or following penetrating keratoplasty or post-refractive (e.g., LASIK) surgery.
- Collect and record baseline clinical information to which fitting examination results can be compared.

B. Initial Lens Power Selection

Standard procedures for determining power of rigid gas permeable contact lenses such as over-refraction may be used, including compensation for vertex distance.

C. Initial Lens Diameter Selection

For keratoconus conditions, lens diameters between 7.0 mm and 21.0 mm are chosen to maximize positioning on the cornea and to minimize lens movement.

For pellucid marginal degeneration, lens diameters are typically between 9.5 mm and 21.0 mm.

For post-surgical indications, a larger lens diameter between 9.0 mm and 21.0 mm is chosen to avoid fitting on or near the graft (suture) line. Lens diameters outside of this range are occasionally used for some eyes.

This guide is only a general recommendation and the specification for an individual patient will depend on the eye care practitioner's judgment.

Lens diameter is primarily a function of the base curve but may be influenced by power (plus lenses require a larger diameter to compensate for weight) and anatomical considerations (small palpebral opening, excessively large pupil, etc.) and the patient's corneal topography.

Scleral Lens Fitting
In scleral lens designs (GP lens where some point of the lens rests on the sclera) lens diameter is a primarily a function of the lens design characteristics of base curve, sagittal depth, and fitting method.

D. Initial Lens Base Curve Selection

For keratoconus, the base curve of the first lens fitted is generally equal to or slightly steeper than the flattest keratometry reading to achieve an apical clearance or apical alignment fitting relationship.

For Pellucid Marginal Degeneration, the base curve chosen is generally flatter than the flattest K reading. It may be equal to the radius of curvature as measured 4 mm from the corneal apex by topography (which is usually flatter). If using K readings, the base curve chosen will be approximately 1.00D flatter than the median K reading.

For Post Penetrating Keratoplasty (Corneal Graft) fitting, initial base curve selection will depend on the shape and position of the graft.

The post-operation cornea may be "Prolate" where the graft is steeper than the surrounding peripheral "host" cornea. Typically, a slightly steeper than K base curve would be used.

The post-operation cornea may be "Oblate", where the graft is flatter (sunken) than the surrounding host cornea. In this case, a base curve flatter than K or a reverse geometry lens may be required.

For post refractive surgical fitting (LASIK), the central cornea is much flatter than a "normal" (non-operated) cornea. Base curve choices are usually 0.50 to 1.00D flatter than the pre-op Flat K reading.

Scleral Lens Fitting
The initial base curve is selected to determine first trial lens. This base curve is generally between 1.50D flatter than the flattest keratometry reading to 2.00D steeper than the steepest keratometry reading to achieve a fit that aligns or provides a slight touch across the corneal surface.

E. Initial Lens Evaluation

Movement
Blink induced lens movement should show downward lens movement with the lid motion (average 1 mm) and then upward with the lid motion (average 1 mm) as with a standard gas permeable contact lens. During the interblink period the lens should have little or no motion (average less than 1 mm). For lens designs over 11.5 mm diameter may exhibit little or no movement.

Scleral Lens Fitting
Lens designs over 11.5 mm diameter exhibit little or no movement

Positioning
The lens should position centrally or slightly inferiorly, as it will tend to migrate to the steepest cornea area. Lens designs over 11.5 mm diameter will most always position centrally.

Characteristics of a Tight (Too Steep) Lens
A lens that is too tight will show reduced movement upon blinking. Bubbles may be detected behind the lens. For lens designs over 11.5 mm diameter the presence of bubbles may not indicate a poor fitting lens.

Characteristics of a Loose (Too Flat) Lens
A lens that is too loose will move excessively on the cornea, following each blink. The lens may ride in either a position that is too high or too low or in an eccentric position. A loose lens is usually uncomfortable for the patient.

Scleral Lens Fitting
Lens designs over 11.5 mm diameter will most always position centrally.

Characteristics of a Tight (Steep, Excessive Sagittal Depth) Lens
Bubbles may be detected behind the lens but with lenses that are larger than 11.5 mm their presence may not indicate a poor fitting relationship.

Characteristics of a Loose (Too Flat, Insufficient Sagittal Depth) Lens
Scleral lenses larger than 11.5 mm diameter generally will never have loose (excessive movement) fitting relationship although they may have a flat lens to cornea fitting relationship. Flat lenses are indicated by excessive bearing on the cornea usually best seen during fluorescein pattern evaluation.

3. Trial Lens Fitting

Trial Lens Fitting
Trial lens fitting is recommended whenever possible. Trial lens fitting allows a more accurate determination of lens specifications for the lens fit and power. Choose the first lens according to the base curve selection criteria for the specific lens design. Trial lenses are essential in fitting patients whose corneal topography is distorted.

Trial Lens Procedure
Select a trial lens and place the lens upon the eye. Evaluate the lens using white light for the following:

Centering
Lenses may not center well due to the unusual corneal topography in patients with keratoconus. Often the lens will position inferiorly over the steepest corneal area.

Scleral Lens Fitting
The scleral lens design will almost always center well due to its large ocular surface coverage area.

Movement
Lens movement should be equivalent to or slightly less than a standard RGP lens.

Scleral Lens Fitting
The scleral lens design will generally exhibit little or no movement.

Evaluate the fluorescein pattern. The fluorescein pattern should show a lens with either mild apical clearance or "leather" touch (alignment) over the steepest conical area. In the periphery there should be another area of alignment and near the edge, a thin band of pooling.

The fluorescein pattern provides the best method for monitoring the fit of the contact lens over time.

Scleral Lens Fitting
The fluorescein pattern should show alignment or slight "feather" touch across the corneal surface. There may be a light band of fluorescein in the periphery where the posterior edge slightly lifts off from the sclera.

4. Special Follow-Up Care

A. With lenses in place on the eyes, evaluate fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The fluorescein pattern provides a guide to lens adaptation. If the lens demonstrates reduced movement, consider exchanging for another of flatter base curve. Usually, a lens with a 0.50 diopters flatter base curve should be the next choice with variations from this based on the judgment of the eye care practitioner. A lens with excessive movement should be replaced with another that is 0.50 diopters steeper base curve.

Scleral Lens Fitting
With lenses in place, evaluate the fitting performance to assure that the criteria of a well fit lens continue to be satisfied. If there is an excessively flat lens to cornea fitting relationship, choose the next steeper (increased sagittal depth) trial lens and evaluate. If there is an excessively steep lens to cornea fitting relationship, choose the next flatter (decreased sagittal depth) diagnostic lens from the manufacturer's trial set. Repeat the trial lens evaluation procedures for centering, movement, and fluorescein pattern. Continue with this process until the optimum fit is achieved.

B. After the lens removal, conduct a thorough biomicroscopy examination to detect the presence of unusual vertical corneal striae in the posterior central cornea and/or corneal neovascularization.
Note: Some vertical striae is typical in advanced stages of keratoconus. The presence of these conditions may be indicative of excessive corneal edema.

The recommended schedule for follow-up visits are the same as standard lenses. Refer to the Follow-Up Care section.

Note: Practitioners should consult their finishing lab for available keratoconus, pellucid marginal degeneration, and post-surgical lens designs. The design parameters must meet the parameters specified in the product labeling.

LENS CARE DIRECTIONS

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

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

1. Rub and Rinse Time

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

WARNING:

- Rub and rinse your lenses for the recommended amount of time to help prevent serious eye infections.
- **Never use water**, saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

2. Soaking and Storing Your Lenses

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

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

3. Lens Case Care

Instruction for Use:

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

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

4. Water Activity

Instruction for Use:
Do not expose your contact lenses to water while you are wearing them.

WARNING:
Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection including, but not limited to, *Acanthamoeba* keratitis. If your lenses have been submersed in water, you should thoroughly clean and disinfect them before insertion. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

5. Discard Date on Solution Bottle

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

WARNING:
Using your solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

6. Basic Instructions

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

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

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

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

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

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

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

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

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

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle and follow instructions. Do **NOT** use enzymatic cleaner with lenses coated with Tangible® Hydra-PEG®.

- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly as recommended by the 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 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 disinfection 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 case with solution as 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.
- Eye care practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- Eye care practitioners may recommend a Weekly Enzymatic Cleaner which can be used to effectively remove protein deposits from Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses. Enzymatic cleaner **not recommended** for use with lenses coated with Tangible® Hydra-PEG®.
- Boston XO_2® and Boston XO_2® with Tangible® Hydra-PEG® Contact Lenses **cannot** be heat (thermally) disinfected.

CARE FOR A STICKING (NON-MOVING) LENS

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

LABORATORY LENS CLEANER-NOT FOR USE WITH BOSTON XO_2® WITH TANGIBLE® HYDRA-PEG® CONTACT LENSES

Residue left by body oils, household solvents, and personal care products may be removed with an enhanced cleaning agent such as Boston® Laboratory Lens Cleaner. This clear, colorless surfactant is for **laboratory and in-office use only**. When lenses are received from the Authorized Boston® Manufacturer, they should be cleaned with Boston® Laboratory Lens Cleaner prior to use of the Boston® Care System and an overnight soak. Lenses exhibiting a non-wetting surface should be cleaned with Boston® Laboratory Lens Cleaner as a method of first choice. **Boston® Laboratory Lens Cleaner is intended for PROFESSIONAL USE ONLY. It is not available for resale or distribution to patients.**

IN-OFFICE LENS MODIFICATIONS NOT FOR USE WITH BOSTON XO_2® WITH TANGIBLE® HYDRA-PEG® CONTACT LENSES

Edge reshaping and surface repolishing can be performed by conventional techniques if the following precautions are observed:

1. Avoid polishing compounds or cleaners that contain ammonia, alcohol, or organic solvents.*
2. Completely remove all traces of adhesive (if double-backed tape is used) with the special authorized solvent.** (The use of any other solvent may cause surface breakdown.) Minimize exposure to the solvent and immediately remove all traces with Boston® Cleaner or Boston ADVANCE® Cleaner followed by a thorough water rinse.
3. Perform the initial lens modifications cautiously because the response of this polymer to these procedures is more rapid than that of silicone acrylate materials.
4. More extensive modifications should not be attempted. Best results will be obtained by using Boston® Professional Cleaning Polish, which is available from Authorized Boston® Manufacturers.
5. The Original Boston® Care System, Boston ADVANCE® Comfort Formula Care System or Boston SIMPLUS® Multi-Action Care System, including the overnight soak, should be used prior to lens dispensing.

CAUTION: Damage may result from improper modifications techniques. Consult your Authorized Boston® Manufacturer or contact Bausch + Lomb for more detailed information.

***WARNING:** Do **not** use solvents such as alcohols, esters, ketones, or chlorinated hydrocarbons (including naphtha, lighter fluid, etc.) since they may damage the lens surfaces and increase the brittleness of the lens.

**Use only the solvent supplied by your lens laboratory and minimize solvent exposure time by rubbing a solvent-saturated cloth over the lens surfaces and quickly removing the solvent with a surfactant. Do not soak the lenses in the solvent.

REMOVAL OF SURFACE DEPOSITS

Deposits are easily removed from the surfaces of Boston XO_2® Contact Lenses. These deposits are best identified by inspecting the cleaned and dried lens with a slit lamp in a dark room using a medium-width illuminating beam.

Surface deposits should be gently removed with Boston® Professional Cleaning Polish, which is available in a kit form with a polishing pad that permits practitioners to manually clean and polish their patient's rigid gas permeable lenses. The Boston® Professional Cleaning Polish and Manual Polishing Machine kit is available from Authorized Boston® Manufacturers.

CAUTION: Applying excessive and prolonged pressure to the lens during the polishing procedure may alter its surface optics. Do **NOT** polish the lenses coated with Tangible® Hydra-PEG®.

REPORTING OF ADVERSE REACTIONS

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

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

HOW SUPPLIED

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

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

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