



BOSTON SIGHT

PACKAGE INSERT

BostonSight SCLERAL

FOR DAILY WEAR

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER

BostonSight SCLERAL
(Optimum Extra – roflufocon D)

Device Identifier: BSSOXA

BostonSight SCLERAL
(Optimum Extreme – roflufocon E)

Device Identifier: BSSOXM

BostonSight SCLERAL
(Optimum Infinite – tisilfocon A)

Device Identifier: BSSINF

BostonSight SCLERAL
(Boston Equalens II® – oprifocon A)

Device Identifier: BSSEII

BostonSight SCLERAL
(Boston XO2® – hexafocon B)

Device Identifier: BSSXO2

IMPORTANT

Please read carefully and keep this information for future use. The eye care practitioner should provide the patient with the wearer's guide that pertains to the patients prescribed lens.

DESCRIPTION OF LENSES

BostonSight SCLERAL daily wear contact lenses are manufactured with a large diameter RGP lens design that vaults over the cornea and rests on the conjunctiva overlying the sclera. The **BostonSight SCLERAL** daily wear contact lenses are lathe cut and fabricated from one of the following fluoro-silicone acrylate rigid gas permeable (RGP) lens materials:

- Optimum Extra - roflufocon D
- Optimum Extreme - roflufocon E
- Optimum Infinite – tisilfocon A
- Boston Equalens II - oprifocon A
- Boston XO2 - hexafocon B

The physical properties of **BostonSight SCLERAL** are as follows:

	roflufocon D	roflufocon E	tisilfocon A	oprifocon A	hexafocon B
Refractive Index	1.4333	1.4332	1.4380	1.4230	1.4240
Light Transmission (clear)	>97%	>97%	n/a	>95%	>95%
Light Transmission (tinted)	>90%	>90%	>91%	>90%	>83%
Specific Gravity	1.166	1.155	1.20	1.24	1.19
Oxygen Permeability (Dk)	100	125	200	85	141
ISO/FATT Method					
Visitint lenses contain one or more of the following color additives conforming to: 21 CFR Part 73 & 74, Subpart D	D & C Green No. 6, FD & C Red No. 17, CI Solvent Yellow 18	D & C Green No. 6, FD & C Red No. 17, CI Solvent Yellow 18	D&C Green No. 6, CI Solvent Yellow No. 18, D&C Violet No. 2 and D&C Red No. 17	D&C Green No.6 and D&C Yellow No.10	D&C Green No. 6; C.I. Solvent Yellow No. 18; D&C Violet No. 2; D&C Red No. 17; C.I. Solvent Yellow No.18
UV Light Blocking (UVB – 280nm – 315nm; UVA 316nm – 380nm)	>98% UVB >95% UVA	>98% UVB >95% UVA	>99% UVB >85% UVA	>95% UVB >97% UVA	>95% UVB >97% UVA

BostonSight SCLERAL is available in the following lens parameters:

Parameter	Range	Tolerance
Base Curve	5.00mm to 9.00mm	± 0.05 mm
Center Thickness	0.05mm to 0.60mm	± 0.02 mm
Diameter	8.00mm to 26.00mm	± 0.10mm
Spherical Power	-25.00 D to +35.00 D (in 0.25D steps)	± 0.12 (0 to <= 5D) ± 0.18 (5 to <= 10.0D) ± 0.25 (10 to <= 15D) ± 0.37 (15 to <= 20D) ± 0.50 (over 20D)

ACTIONS

When placed on the eye for therapeutic use, the **BostonSight SCLERAL** daily wear contact lenses replace or support impaired ocular surface function. Additionally, the **BostonSight SCLERAL** daily wear contact lenses act as a refracting media to focus light rays on the retina.

CAUTION

CAUTION – Non-sterile. Clean and condition lenses prior to use.

CAUTION:

**FEDERAL LAW RESTRICTS THIS DEVICE TO SALE
BY OR ON THE ORDER OF A LICENSED PRACTITIONER.**

Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant

numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health must be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

INDICATIONS

BostonSight SCLERAL daily wear contact lenses are indicated for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and non aphakic persons. Also, the lenses may be prescribed in 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 surgery.

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.

BostonSight SCLERAL daily wear contact lenses 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 **BostonSight SCLERAL** daily wear contact lenses are also indicated for therapeutic use in eyes with ocular surface disease including, but not limited to, 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 **BostonSight SCLERAL** daily wear contact 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 **BostonSight SCLERAL** daily wear contact lenses when any of the following conditions are present:

- * Acute and subacute inflammation or infection of the anterior chamber of the eye.
- * Any systemic disease that may affect the eye and would be worsened by wearing the device.
- * Any eye disease, injury, or abnormality, other than irregular astigmatism, corneal degeneration or dystrophy that compromises the corneal endothelium or the ocular surface in ways that would be worsened by wearing the device.
- * Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing the device or use of care solutions.
- * Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for **BostonSight SCLERAL**.
- * Any active corneal infection (bacterial, fungi, or viral)
- * If eyes become red or irritated.
- * Patients unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS

- * The safety and effectiveness of lenses depends on proper use.
- * **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 direction 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; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR CONTACT LENSES AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.**
- * An eye care practitioner should be consulted regarding proper use.
- * Infection, with possible permanent damage to vision, could result from the failure to strictly follow recommended directions for use and lens care procedures.
- * All contact lens wearers must see their eye care practitioner as directed.
- * Consult your eye care practitioner regarding the use of **BostonSight SCLERAL** in certain atmospheric conditions that can cause irritation to the eye.
- * Daily wear contact lenses are not indicated for overnight wear, and patients should be instructed not to wear contact lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when contact lenses are worn overnight.
- * Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

PRECAUTIONS

Special Precautions for eye care practitioner and/or physician:

Warning: Inspect contact lens packaging for leakage when lenses are wet shipped. If the packaging is damaged or leaking, throw away damaged packaging and replace with a new contact lens case and refill with new cleaning, disinfection and storage solution.

Prior to dispensing contact lenses that have been shipped wet, it is important to **THOROUGHLY RINSE**

all solution from the lens since it could sting and cause irritation if instilled directly in the eye. All lenses whether shipped wet or dry should be cleaned with daily cleaner and rinsed with fresh, sterile rinsing solution prior to applying to patient's eye.

When lenses are shipped/stored wet, the solution needs to be replaced with fresh, sterile, and unexpired solution every 30 days from initial manufacture date.

- * Clinical studies have demonstrated that contact lenses manufactured from (rofluocon D, rofluocon E, tisilfocon A, oprifocon A, & hexafocon B) are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in this lens material.

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. The continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

- * For the most accurate fluorescein interpretation, it is recommended that the blue cobalt and the yellow Wratten filter be used. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in eye use.
- * Thoroughly rinse the **BostonSight SCLERAL** daily wear contact lenses with fresh, sterile saline or rinsing solution prior to application.
- * 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.

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

- * Different solutions cannot always be used together, and not all solutions are safe for use with all contact lenses. Use only recommended solutions that are fresh and sterile.
- * Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection. Always use **FRESH, STERILE, UNEXPIRED** lens care solutions. Always follow directions in the package inserts or the directions of your eye care provider for the use of contact lens solutions. 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 solution for

-
- lubricating or rewetting lenses.
- * Always wash and rinse hands before handling contact lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to apply lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base.
 - * Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
 - * Carefully follow the handling, application, removal, cleaning, disinfection, storing and wearing instructions in the patient instructions for the **BostonSight SCLERAL** daily wear contact lenses and those prescribed by the eye care practitioner.
 - * Never wear lenses beyond the period recommended by the eye care practitioner.
 - * Always inspect contact lenses for chips or cracks prior to application.
 - * If aerosol products such as hair spray are used while wearing contact lenses, exercise caution and keep eyes closed until the spray has settled.
 - * Always handle the **BostonSight SCLERAL** daily wear contact lenses carefully and avoid dropping them.
 - * Avoid all harmful or irritating vapors and fumes while wearing contact lenses.
 - * Ask the eye care practitioner about wearing **BostonSight SCLERAL** daily wear contact lenses during sporting activities.
 - * Inform the doctor (health care practitioner) about being a contact lens wearer.
 - * Never use tweezers or other tools to remove contact lenses from the lens case unless specifically indicated for that use. Pour the lens into the hand.
 - * Do not touch the lens with fingernails.
 - * Always contact the eye care practitioner before using any medicine or medications in the eyes.
 - * Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lens.
 - * 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 lens was first placed on eye.
- * Feeling that something is in the eye such as a foreign body or scratched area.
- * Excessive watering (tearing) or the eye.
- * Unusual eye secretions.
- * Redness of the eye.
- * 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 BOSTONSIGHT SCLERAL DAILY WEAR CONTACT**

LENSES.

- * If discomfort or problems 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 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 and rinse the lenses, then reapply them. After re-application, if the problem continues, the patient should **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 LENS OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION** of the problem and prompt treatment to avoid serious eye damage.

During therapeutic use, an adverse effect may be due to the original disease or injury or may be due to the effects of wearing the contact lenses. There is a possibility that the existing disease or condition might become worse when a contact lens is used to treat an already diseased or damaged eye. The patient should be instructed to avoid serious eye damage by contacting the eye care professional **IMMEDIATELY** if there is any increase in symptoms while wearing the device.

FITTING

Patient Selection

Patient communication is vital. Patients who require visual correction but cannot adhere to the recommended care of **BostonSight SCLERAL** daily wear contact lenses should not be provided with this lens. All necessary steps in lens care and all precautions and warnings should be discussed and understood by the patient (*Review Package Insert with patient*).

General Information

Standard fitting principles and techniques are applicable for the **BostonSight SCLERAL** daily wear contact lenses. A diagnostic lens fitting procedure is recommended, although not always required.

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 were not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health must be carefully weighed against the patient's need for refractive correction. Therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

Fitting Procedure

The basis for the **BostonSight SCLERAL** daily wear contact lens fitting system revolves around the observation that the management of irregular corneal conditions such as; keratoconus, pellucid marginal

degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery may require additional corneal clearance and adequate haptic alignment along the supporting sclera if the nature of the corneal irregularities do not allow for the fitting of a corneal lens. Parameters that are standard in the lens design are calculated for adequate corneal clearance, haptic alignment, maximum comfort and enhanced visual acuity. Criteria of fit include good centration, no translational movement or rocking, no air intrusion, and absence of compression or impingement.

The principal design requirement for the **BostonSight SCLERAL** fluid-ventilated scleral lens is that the shape of its bearing surface be aligned with that of the supporting sclera. Adequate assessment relies on the blanching patterns of the episcleral blood vessels under the haptic to document the presence and location of excessive scleral compression. The haptic vascular pattern (HVP) is for the scleral lens what the fluorescein pattern is for the corneal RGP lens. The ideal haptic-sclera relationship shows neither vascular compression nor air bubbles under the haptic.

Diameter selection

As the diameter of a lens is decreased, the area of its haptic bearing surface becomes smaller. Smaller bearing surfaces increase scleral compression. This is not usually clinically significant for lenses having diameters 18.0mm or more. Large sizes, i.e., 19mm are useful for large globes such as those with keratoectasia and high myopia.

Sagittal Height.

The recommended corneal apical clearance is 200 μ to 400 μ . Although excessive vaulting over the cornea may reduce somewhat the amount of oxygen available to the cornea, it is preferable to err on the side of creating generous corneal clearance in order to avoid **any** apical compression after the lens has settled. Our recommended starting point is a 3mm sagittal height at the 12mm chord.

Base curve

The **BostonSight SCLERAL** daily wear contact lens design decouples base curve changes from effects in corneal clearance and sagittal height selection. In general, base curves in the range of 7.8 to 8.0 are the most useful since steeper base curves tend to crowd the peripheral surfaces of non-ectatic corneas and therefore require higher central sagittal heights. On the other hand, lenses with flatter base curves may increase the need for plus power and the resulting increased lens thickness will reduce its oxygen transmissibility. This is usually only significant for grafted corneas with marginal endothelial function. Our base curve starting point is 8 mm.

Front surface optics

If over-refraction does not improve vision to the expected level through a lens with a spherical front surface, it is important to check for residual astigmatism which, if significant, should be corrected with glasses. If no residual astigmatism is found, then the presence of residual higher order aberrations should be suspected. Acuity should be assessed with lenses having different front surface eccentricities.

Fitting eyes s/p LASIK or RK

The corneal topography of these eyes is characterized by a flat central cornea surrounded by an elevated zone. In fitting these eyes, the base curve should be sufficiently flat to provide adequate clearance over the intermediate corneal bulge. A base curve radius of 8.5mm usually suffices – which falls within the standard base curve parameters in the **BostonSight SCLERAL** diagnostic lens set. This also reduces the required minus power of these lenses. Residual higher order aberrations should be suspected if the best corrected visual acuity is suboptimal and not accountable by other ocular pathology. In such cases, the

fitter should evaluate best corrected visual acuity of lenses having front surface eccentricity and check for residual astigmatism.

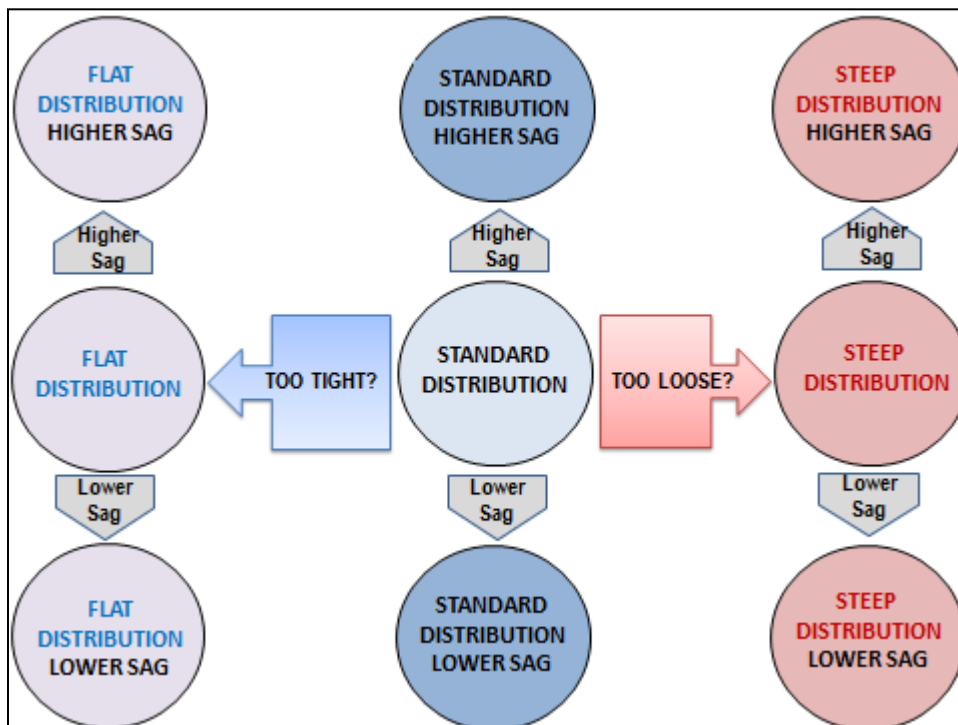
Lens Parameter Availability

- Diameters* 16.0 mm to 26.0 mm (0.5mm steps)
- Base Curves* 9.0 mm to 5.00 mm (0.10 mm steps)
- Sphere power -25.00 Diopters to +35.00 Diopters
- *Custom parameters available

Diagnostic Lens Set

Successful fitting requires the effective use of diagnostic lenses. Each set contains 9 diagnostic lenses per eye per diameter. Two additional lenses per eye are included for residual higher order aberration control and best corrected visual acuity. Lens selection and fitting is designed to be hierarchical for each specific diameter (i.e., 18.0, 18.5, or 19.0mm) to simplify the fitting approach as described in the schematic below (Figure AA). The selection process starts at the center with a standard distribution and standard sagittal height. The practitioner can choose next lens by going up and down in sagittal height within each distribution specified: Standard, Flat, or Steep. If standard distribution is too loose, the practitioner will choose the Steep Distribution Lens with standard sagittal height. Within this distribution, a choice of higher or lower sagittal heights are available in order to achieve adequate corneal clearance. If the standard distribution is tight fitting, the practitioner will choose the Flat Toric Distribution. Within this distribution, a choice of higher or lower sagittal heights are available in order to achieve adequate corneal clearance.

Figure AA.



Recommended 18 Lens Diagnostic Set (Plus 4 extra lenses for residual aberration control and best corrected visual acuity assessment purposes):

Fitting goals for BostonSight SCLERAL

The following are the fitting goals of **BostonSight SCLERAL** after it has settled for 20-30 minutes:

1. Corneal clearance: The thickness of the fluid compartment over the corneal apex is approximately 200 μ to 400 μ (in comparison, the center thickness (CT) of the normal cornea is about 500 μ).
2. Vaulting should occur at limbal area
3. Episcleral blood vessels underlying the haptic are not compressed for adequate haptic scleral alignment.
4. Air bubbles do not intrude under the haptic or optic zone *after* the lens has been applied bubble-free.
5. The lens centers well and is virtually motionless on blinking.
6. The edge of the lens does not impinge on bulbar conjunctiva.
7. The imprint of the edge of the lens on the bulbar conjunctiva, if present, is not sharply demarcated and does not stain with fluorescein after lens removal.

FITTING PRINCIPLES OF BOSTONSIGHT SCLERAL

The process of fitting **BostonSight SCLERAL** is based on identifying the best fitting trial lenses and adapting their geometries and power to create the eye-specific lens. The steps are as follows:

1. Identify the trial lens having the best initial fit (process described above).
2. Evaluate its fit after the appropriate settling time.
3. When indicated, replace it with one having more appropriate parameters.
4. Repeat the process until the best fitting trial lens is identified.
5. Perform over-refraction to determine best visual acuity
6. Order the lens.
Note: The eye-specific lens design may be a composite of the parameters of several trial lenses.
7. Repeat the cycle with the ordered lens.

Fitting BostonSight SCLERAL with Topography

Selection for a **BostonSight SCLERAL** can be aided with the use central corneal curvature clues derived from keratometry reading or simK obtained from video keratography.

Steep Sim K Value	Suggested Sagittal Height at 6mm chord
Up to 55D	2.6mm
55D to 75D	3.0mm
$\geq 75D$	3.4mm

Determining Lens Power

The most accurate method for determining lens power for a patient with irregular corneal conditions is to over-refract over the final diagnostic lens. The traditional rules of SAM FAP (Steeper Add Minus, Flatter Add Plus) do not always translate accurately with keratoconus patients.

Fitting Tips

When ordering **BostonSight SCLERAL** make certain to specify the:

1. Eye
2. Distribution
3. Diameter
4. Sagittal Height
5. Power
6. Eccentricity

Troubleshooting

Post Lasik and RK eyes:

It is preferable to choose flatter base curves (i.e. 8.5mm) in order to clear the intermediate corneal bulge and avoid requiring high minus lens power.

Accumulation of debris in the fluid reservoir:

This is common in eyes with distorted corneas which also have a dry eye component. It requires periodic lens removal to replace the fluid in the lens reservoir. The use of more viscous fluid in the lens reservoir, such as preservative-free Refresh Celluvisc (Allergan, Inc.; Drug Identification Number (DIN): 00870153), can delay the accumulation of debris under the lens.

The possibility of reducing the inflow of tears into the fluid compartment should be assessed by:

- a. Re-evaluating the toric distribution in the trial lens or increasing the toricity of the individual haptic meridian.
- b. Decreasing the lens diameter which, by moving the bearing surface of the haptic to a more rotationally symmetrical scleral surface, may improve the effectiveness of lowering (steepening) the haptic.

Coating of the lens:

Patients with concomitant dry and chronic external inflammatory eye disease can expect mucous debris to accumulate on the front surface of their devices despite treatment in a plasma chamber. All silicon-containing polymers have amphiphilic surfaces. This means that regardless of low wetting angles in aqueous media, their surfaces become very hydrophobic when dry. In this state, lipid-containing mucous becomes strongly adherent and can only be removed by mechanical means, such as removing the devices and rubbing their surfaces with Boston Conditioning Solution (Regular Formula) followed by a saline rinse or in some instances just by removing the devices and simply rubbing their surfaces with preservative-free saline.

Hooding of the limbal bulbar conjunctiva:

Loose bulbar conjunctiva is often seen overlapping the peripheral cornea during lens wear. This can be quite impressive. Nevertheless, if the redundant conjunctival tissue is flat, the condition is benign. On the other hand, if limbal bulbar conjunctiva is pulled against the back surface of the lens, fluid has been imbibed under this tissue **and** there is significant resistance to lens removal, excessive lens suction is present. This requires a re-design to establish adequate venting by improving haptic scleral alignment.

Peripheral arcuate corneal imprint:

The presence of an arcuate corneal depression adjacent to the limbus indicates lens compression over the corneal periphery. This can be resolved by a flatter base curve and, if indicated, increasing the lens sagittal height.

Diffuse, fine SPK: (The following should be ruled out for lens related causes)

- a. Residual hydrogen peroxide. This is always associated with stinging on lens application and may indicate the need for more a more complete saline rinse prior to lens insertion or for replacing the platinum catalyst if this system is used for neutralization.
- b. Sensitivity to wetting/soaking solution used for overnight storage (if any). In these cases, overnight hydrogen peroxide disinfection is recommended.
- c. SPK that develops after lens removal: Patients (or guardians) should be questioned to rule-out nocturnal lagophthalmos. Adequate nightly lubrication and tape tarsorrhaphy may be indicated as a therapeutic trial when the lens is removed.

Lens-related bulbar conjunctival injection:

Common causes include:

- a. Pinguecula, especially the more diffuse type.
- b. Excessive haptic compression and/or edge impingement.
- c. Inadequate purging of hydrogen peroxide.
- d. Sensitivity to constituents of contact lens wetting solutions if used for lens soaking.

Edge impingement:

This refers to localized edge compression not due to scleral toricity. (Compression is not present under the opposite meridian.) The following are possible causes of localized peripheral compression or edge impingement:

- a. Thick, elevated Tenon's capsule: This requires an appropriate reduction in the lens diameter.
- b. Raised pinguecula and pterygia: The choice of lens diameter is determined by the distance of the lesion from the limbus. If it is located more peripherally, smaller lens diameters can be considered if they **do not impinge on the lesion**. More often it is necessary to increase the lens diameter so that its haptic rests *over* the elevated tissue.
- c. Sectorial/meridional localized edge compression. This is usually resolved by elevating the haptic in the specified meridian.

Lens awareness/discomfort:

In the absence of a lens edge imprint on the bulbar conjunctiva, one should consider the possibility that the edge bevel is too high. This may be difficult to identify by slit lamp examination. Resolution is often achieved by empirically changing the profile of the lens edge, bevel or diameter.

Blurred vision that develops after lens application:

Common causes include:

- a. Deposits accumulating on the front surface of the lens.
- b. Debris accumulating in the fluid reservoir.
- c. The development of corneal microcystic epithelial edema. This is characterized by hazy vision that persists for a period of time after lens removal and the patient's observation of rainbows around light sources.

Development of hypertrophic bulbar conjunctival lesion coincident with the edge of the lens:

This is due to chronic edge impingement and its resolution requires a significant change in the lens diameter, either smaller by at least 1mm if this avoids *any* edge impingement in this area, or larger so that the lens rides over the hypertrophic tissue.

Discrete round or oval depression of the corneal surface present immediately after lens removal:

If it pools fluorescein dye, does not stain and resolves rapidly, it is most likely a dellen due to a sequestered air bubble during lens wear.

Rippled texture of the corneal surface immediately after lens removal:

This is common and benign. It probably is due to the absence of the normal shearing forces of blinking that serve, among other things, to smooth the mucin layer on the corneal surface.

Follow-up Examinations

- * Within one week of lens dispensing
- * After three weeks of lens wear
- * After seven weeks of lens wear
- * After each six-month period of lens wear.

At the follow-up examinations, the patient should report good subjective quality of vision. Adaptation to vision of the **BostonSight SCLERAL** daily wear contact lenses should occur almost immediately and should definitely be reported within the first (1 week) follow-up visit. At these follow-up visits the practitioner should:

1. Check distance and near acuity with lenses in place.
2. Over refract to verify lens prescription.
3. Observe the position of the lens on the cornea. The lens should be centered and move on upward gaze and with a blink.
4. Invert the lids to examine the tarsal conjunctiva and check for incidence of giant papillary conjunctivitis.
5. Remove the lens. Check corneal curvature. There should be no substantial changes in either meridian.
6. Perform a slit-lamp examination with and without Fluorescein. Check for corneal edema, corneal abrasion, vascularization, corneal infiltrates, and perilimbal injection.
7. Clean the lens with a prophylactic surfactant cleaner, and examine for deposits, foreign bodies or physical imperfections of the lens surface.
8. Re-apply the lens only after all residual Fluorescein has dissipated from the eye.

Lens Handling

Wash and rinse hands thoroughly, making certain all soap residues have been rinsed away before drying with a lint-free towel. *It is suggested to wet the lens while in the eye using lubricating and rewetting drops before removal.* Always start with the right lens first in order to avoid mixing the lenses

In-Office Cleaning, Disinfecting and Storage

When packaged wet, the **BostonSight SCLERAL** daily wear contact lenses received in the eye care practitioner's office is received non-sterile in an individual plastic lens case and labeled as to the parameters of the lens contained. When lenses are shipped/stored wet, the solution needs to be replaced

every 30 days from initial manufacture date. The solution shall be Fresh, Sterile, Unexpired and from a newly opened bottle.

Prior to dispensing, it is important to THOROUGHLY RINSE all solution from the lens since it could sting and cause irritation if instilled directly in the eye. Lenses should be cleaned with daily cleaner and rinsed with sterile, rinsing solution before applying to patients' eye.

When packaged dry, the **BostonSight SCLERAL** daily wear contact lenses received in the eye care practitioner's office is received non-sterile in an individual plastic lens case and labeled as to the parameters of the lens contained. The lens should be cleaned and rinsed prior to dispensing to the patient. Reference cleaning section for procedures for cleaning.

Chemical Not-Heat Lens Care System

A daily cleaner for rigid gas permeable contact lenses, sterile rinsing solution and hydrogen peroxide disinfection solution, or multi-purpose solution should be used to clean, rinse and chemically disinfect the **BostonSight SCLERAL** daily wear contact lenses. After cleaning the lens, rinse with a liberal amount of fresh rinsing solution to remove loosened debris and traces of cleaner. The lens should then be placed in its original plastic lens case with enough fresh disinfecting solution to completely submerge the lens. To ensure disinfection, the lens must remain in the disinfecting solution for the recommended period of time as written on the disinfecting solution bottle. Before re-application, lenses should be rinsed with fresh, sterile rinsing solution.

Enzymatic Cleaning

The eyecare practitioner may recommend enzyme cleaning. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the wellbeing of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine daily cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

Storage

The **BostonSight SCLERAL** daily wear contact lenses must be stored dry after disinfection in the individual plastic lens case.

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER

WEARING SCHEDULE

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

Close professional supervision is necessary for therapeutic use of the **BostonSight SCLERAL** daily wear contact lenses, and patient compliance will be critical to the success of this program. Since in these cases the cornea may already be compromised, the cornea must be examined carefully and monitored continually to ensure that the device is not interfering with the condition or healing

process.

The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

BostonSight SCLERAL is indicated for daily wear. The suggested wearing time for these devices is:

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

*if the lenses continue to be well-tolerated

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE BOSTONSIGHT SCLERAL DAILY WEAR CONTACT LENSES ARE SAFE TO WEAR DURING SLEEP.

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:

* **Basic Instructions:**

Care of contact lenses takes very little time and involves three essential steps – **CLEANING, RINSING AND DISINFECTION**. Each step in itself is important, and one step is not to be replaced by the other. Always wash, rinse and dry hands before handling contact lenses. Always use **FRESH, STERILE, UNEXPIRED** lens care solutions. Use the recommended chemical (not heat) lens care system. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS ADVISED BY YOUR EYE CARE PROVIDER**. Do not use non-compatible lens care products.

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** daily. **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 after each use and allowed to dry. The case must be refilled with fresh, sterile disinfection solution prior to disinfecting the lenses. Eye care practitioners may recommend a lubricating/rewetting solution, which can be used to rewet (lubricate) lenses while they are being worn to make them more comfortable.

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.

* **Specific Instructions for Use and Warnings:**

a. Disinfecting the Lenses

Instruction for Use:

- Use only fresh multi-purpose or hydrogen peroxide (contact lens disinfecting) solution each time the lenses are disinfected.

WARNING:

- Do not reuse or “top off” old solution left in the 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 the case.

b. Rub, Rinse and Soak Time

Instruction for Use:

- Rub and rinse the lenses according to the recommended lens rubbing and rinsing times in the labeling of the multi-purpose or daily cleaning solution to adequately clean the lenses.
- Soak the lenses in the multi-purpose or hydrogen peroxide solution according to the labeling instructions to allow completion of disinfection process. Removing before minimum soak time will result in incomplete disinfection and possible eye irritation or injury.

WARNING:

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

c. Lens Case Care

Instruction for Use:

- Empty and 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 or rinsing solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning

methods. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.

- Replace the lens case according to the directions given by the eye care professional or the labeling that came with the case.
- Contact lens cases can be a source of bacterial growth.

WARNING:

- Do not rinse the lenses or the lens case with water or any non-sterile solution. Only use fresh multi-purpose solution or fresh rinsing solution to prevent contaminating the lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

d. Water Activity

Instruction for Use:

- Do not expose the contact lenses to water while wearing them.

WARNING:

- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the lenses have been submersed in water when swimming in pools, lakes or oceans, the patient should **IMMEDIATELY REMOVE THEM**. Lenses should be cleaned and disinfected prior to re-applying. The patient should ask the eye care practitioner (professional) for recommendations about wearing the lenses during any activity involving water.

e. Discard Date on Contact Lens Solution Bottles

Instruction for Use:

- Discard any remaining solution after the recommended time period indicated on the bottle of cleaning, rinsing, disinfecting or multipurpose contact lens solution.
- The Discard date refers to the time the patient can safely use contact lens care product after the bottle has been opened. It is not the same as the expiration date, which is the last date that the product is still effective before it is opened.

WARNING:

- Using any contact lens solutions beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.
- To avoid contamination, DO NOT touch tip of container to any surface. Replace cap after using.
- To avoid contaminating the solution, DO NOT transfer to other bottles or containers.

*** Lens cleaning, rinsing, disinfection, and storage:**

Clean one BostonSight SCLERAL daily wear contact lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended rinsing solution to

remove the cleaning solution, mucus, and film from the lens surface, and put lens into correct chamber of the lens disinfection case. Then repeat the procedure for the second lens. After cleaning and rinsing, **disinfect** lenses using the system recommended by the manufacture and/or the eye care practitioner. To store lens, remove from disinfection case, dry with a soft towel and store dry in a screw-top contact lens case until ready to wear. **BostonSight SCLERAL** lenses should not be worn for the minimum time required each day to disinfect the lenses.

* **Lens Care Regimen:**

Patients must adhere to the lens care regimen recommended by their eye care practitioner for the care of **BostonSight SCLERAL** daily wear contact lenses. Failure to follow this procedure may result in development of serious ocular infections

* **Storage:**

The **BostonSight SCLERAL** daily wear contact lenses must be stored dry in an individual plastic case.

* **Chemical (NOT HEAT) Lens Disinfection:**

1. Wash and rinse your hands thoroughly BEFORE HANDLING LENSES.
2. After removal of lenses, **CLEAN** the lenses by applying three drops of cleaning solution to each surface. Then rub the lens between your fingers for 15 seconds.
3. **AFTER CLEANING**, thoroughly rinse both surfaces of the lens thoroughly with a steady stream of **fresh, sterile unexpired** rinsing solution for approximately 10 seconds.
4. Fill the contact lens case with the recommended disinfection solution and place lenses in the proper cells for the time specified on the solution label.

Note: **DO NOT HEAT THE DISINFECTION SOLUTION AND LENSES.**

Caution: Lenses that are chemically disinfected may retain ingredients from the disinfecting solution, which may be irritating to the eyes. A thorough rinse in fresh, sterile rinsing solution prior to placement on the eye should reduce the potential for irritation.

- When using hydrogen peroxide lens care systems, **the patient should use the lens case recommended by their eye care provider.** Please note that the platinum catalyst from the hydrogen peroxide system must be used in order to neutralize the solution. Failure to use the platinum catalyst will result in severe stinging, burning, and injury to the eye. Following disinfection with a peroxide system, the lenses should be rinsed with sterile rinsing solution.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

The eyecare practitioner may recommend enzyme cleaning. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the wellbeing of the patient's lenses and eyes. If these deposits are not removed, they can

damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine daily cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

RECOMMENDED LENS CARE PRODUCTS

BostonSight SCLERAL daily wear contact lenses should be disinfected using only a chemical (not heat) disinfection system. The eyecare practitioner should recommend a care system that is appropriate for **BostonSight SCLERAL** daily wear contact lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed. The following lens care products are recommended (or other lens care systems as recommended by your eye care practitioner).

LENS CARE TABLE

Product Purpose	Lens Care System
Daily Cleaning	1) OPTIMUM ESC Extra Strength Cleaner (Lobob) 2) Boston [®] SIMPLUS Multi-Action Solution (Bausch & Lomb)
Cleaning, Disinfecting and Soaking.	1) OPTIMUM CDS Cleaning, Disinfecting and Storage Solution (Lobob) 2) Boston [®] SIMPLUS Multi-Action Solution (Bausch & Lomb)
Disinfecting H ₂ O ₂	1) Clear Care [®] 3% Hydrogen Peroxide Cleaning & Disinfecting Solution (Alcon) 2) Generic equivalent
Rinsing	1) PuriLens Plus Preservative Free Saline (The Lifestyle Company) 2) LacriPure Saline Solution (Menicon Co.)
Wetting & Lubricating	1) OPTIMUM GP wetting and rewetting (Lobob) 2) Boston [®] Rewetting Drops (Bausch & Lomb) 3) Refresh Plus DPS 5mg/ml (Allergan)

EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should:

REMOVE CONTACT LENSES AND FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED:

The **BostonSight SCLERAL** daily wear contact lenses may be shipped (non-sterile) “dry” or “wet” in a polypropylene contact lens case. The primary container for shipping the **BostonSight SCLERAL** daily wear contact lenses is the Bausch & Lomb Frequent Replacement Contact Lens Case.

When shipped “wet”, **BostonSight SCLERAL** daily wear contact lenses are shipped Boston SIMPLUS Multi-Action Solution (Bausch & Lomb, Inc.; MDL: 102533).

The packing slip is marked with the base curve, dioptic power, diameter, center thickness, material, color, material UDI#, lot number and the initial packaging date.

REPORTING OF ADVERSE REACTIONS:

Practitioners should report any adverse reactions within 5 days to BostonSight. Additional Fitting Guides, Package Inserts and Patient Guides are available from:

BostonSight TECH, Inc.

464 Hillside Avenue
Suite 205
Needham, MA 02494
USA
www.bostonsight.org

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.

Manufactured By:

BostonSight TECH, Inc.

464 Hillside Avenue
Suite 205
Needham, MA 02494
USA
(888)-SCLERAL



BOSTON SIGHT

PATIENT INSTRUCTION / WEARER'S GUIDE

BostonSight SCLERAL

For DAILY WEAR

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.

CONGRATULATIONS:

You have just received your new **BostonSight SCLERAL** daily wear contact lenses. This booklet has been prepared to help you care for it. Please read it carefully and follow the instructions so that you receive full satisfaction from your lens.

PRACTITIONER: _____

ADDRESS: _____

TELEPHONE: _____

<i>Lens Parameters</i>	TYPE	POWER	DIAM.	BC	LOT#	
Right Lens						
Left Lens						

Disinfection Solution: _____

Rinsing Solution: _____

Daily Cleaner: _____

Lubricating Solution: _____

INTRODUCTION:

Your **BostonSight SCLERAL** daily wear contact lenses are made of a highly purified, hydrophobic polymer with properties different from conventional rigid lenses. Tooled to optical precision, comfort can be immediate. You are cautioned, however, to follow the initial wearing time schedule prescribed by your practitioner and not to over wear the lenses simply because they remain comfortable. Your eye care practitioner will determine your appropriate wearing schedule.

The life of your **BostonSight SCLERAL** daily wear contact lenses will depend to a large extent on how you handle and care for them. As with all precision devices, proper use will assure you the benefits of convenience, comfort, and confidence in your lenses.

Read this Wearer's Guide carefully. It contains the information you need to know to wear, handle, and care for **BostonSight SCLERAL** daily wear contact lenses. If you are in doubt about any instructions, request clarification from your eye care practitioner.

WEARING RESTRICTIONS and INDICATIONS:

Indication for Use:

BostonSight SCLERAL daily wear contact lenses are indicated for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and non aphakic persons. Also, the lenses may be prescribed in eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, keratoglobus, post-LASIK ectasia, or following penetrating keratoplasty or refractive surgery.

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.

BostonSight SCLERAL daily wear contact lenses 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 **BostonSight SCLERAL** daily wear contact lenses are also indicated for therapeutic use in eyes with ocular surface disease including, but not limited to, 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 **BostonSight SCLERAL** daily wear contact lenses may concurrently provide correction of refractive error.

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

DO NOT WEAR **BostonSight SCLERAL** daily wear contact lenses WHILE SLEEPING.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the **BostonSight SCLERAL** daily wear contact lenses when any of the following conditions are present:

- * Acute and subacute inflammation or infection of the anterior chamber of the eye.
- * Any systemic disease that may affect the eye and would be worsened by wearing the device.
- * Any eye disease, injury, or abnormality, other than irregular astigmatism, corneal degeneration or dystrophy that compromises the corneal endothelium or the ocular surface in ways that would be worsened by wearing the device.
- * Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing the device or use of care solutions.
- * Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for **BostonSight SCLERAL**.
- * Any active corneal infection (bacterial, fungi, or viral)
- * If eyes become red or irritated.
- * Patients unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS:

- * The safety and effectiveness of lenses depends on proper use.
- * **PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.** It is essential that you follow your eye care practitioner's direction 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; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR CONTACT LENSES AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.**
- * An eye care practitioner should be consulted regarding proper use.
- * Infection, with possible permanent damage to vision, could result from the failure to strictly follow recommended directions for use and lens care procedures.
- * You must see your eye care practitioner as directed.
- * Consult your eye care practitioner regarding the use of **BostonSight SCLERAL** in certain atmospheric conditions that can cause irritation to the eye.
- * Daily wear contact lenses are not indicated for overnight wear, and you are instructed not to wear the **BostonSight SCLERAL** daily wear contact lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when contact lenses are worn overnight.

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

PRECAUTIONS:

- * CAUTION – Non-sterile. Clean and condition lenses prior to use.
- * Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions that are fresh and sterile. Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in chemical disinfection only. Always use **FRESH, STERILE UNEXPIRED** lens care solutions. Always follow directions in the package inserts or the directions of your eye care provider for the use of contact lens solutions. 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 solution for lubricating or wetting lenses.
- * Always wash and rinse hands before handling contact lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to apply lenses before putting on makeup. Water-base cosmetics are less likely to damage contact lenses than oil-base.
- * Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- * Carefully follow the handling, application, removal, cleaning, disinfection, storing and wearing instructions in the Patient Instructions for the **BostonSight SCLERAL** daily wear contact lenses and those prescribed by your eye care practitioner.
- * Never wear lenses beyond the period recommended by your eye care practitioner.
- * Always inspect contact lenses for chips or cracks prior to application.
- * 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 contact lenses carefully and avoid dropping them.
- * Avoid all harmful or irritating vapors and fumes while wearing lenses.
- * Ask the eye care practitioner about wearing **BostonSight SCLERAL** daily wear contact lenses during sporting activities.
- * Inform the doctor (health care practitioner) about being a contact lens wearer.
- * Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. Pour the lens into the hand.
- * Do not touch the lens with fingernails.
- * Always contact the eye care practitioner before using any medicine or medications in the eyes.
- * Always inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lens.
- * As with any contact lens, follow-up visits are necessary to assure the continuing health your eyes. You should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS:

The following problems may occur:

-
- * Eyes stinging, burning, itching (irritation), or other eye pain.
 - * Comfort is less than when lens was first placed on eye.
 - * Feeling that something is in the eye such as a foreign body or scratched area.
 - * Excessive watering (tearing) of the eye.
 - * Unusual eye secretions.
 - * Redness of the eye.
 - * 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 YOUR LENSES.**

- * If discomfort or problems stops, then look closely at the lens. If the lens is in any way damaged, **DO NOT PUT THE LENS BACK ON YOUR EYE.** Place the lens in the storage case and contact your eye 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 and rinse, the lenses before reapplying them. After reapplication, if the problem continues, you should **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. **KEEP LENS OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION** of the problem and prompt treatment to avoid serious eye damage.

- * During therapeutic use, an adverse effect may be due to the original disease or injury or may be due to the effects of wearing the contact lenses. There is a possibility that the existing disease or condition might become worse when a contact lens is used to treat an already diseased or damaged eye. To avoid serious eye damage, contact your eye care professional **IMMEDIATELY** if there is any increase in symptoms while wearing the device.

PERSONAL CLEANLINESS and LENS HANDLING

Before Handling Your lenses:

Cleanliness is an important aspect of contact lens care.

Before handling your **BostonSight SCLERAL** daily wear contact lenses, always wash and rinse your hands thoroughly and dry them with a lint-free towel. Do not use soaps, lotions, cold creams, or perfumes that leave a residue on your hands. Avoid using medications, creams, deodorants, make-up, after shave lotions, or similar items prior to touching your lenses. When hair spray is used, the eye must be kept closed until the spray has settled. Take care in handling your lenses.

IMPORTANT: Always avoid touching your lenses with your fingernails or other sharp objects. Use only your fingertips.

NEVER WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE LENS MAY BE LOST.

1. You will need a soft towel to be placed on top of a clean work surface where you will apply your lens(es). You will need the following supplies:
 - a. An application plunger
 - b. A removal plunger
 - c. A small mirror
 - d. Preservative-free saline, prescribed for you

Handling and Placing the Lenses on the eye:

1. Wash and rinse your hands thoroughly
2. Dry your hands with a lint free towel
3. To avoid the possibility of lens mix-ups, always start with the same lens first.
4. Empty the contents of the case (i.e. the lens) into the palm of your hand. With the other hand, GENTLY grasp the lens by the edges. Note: the lens should be wet during this process.
5. Before applying the lens, rinse well with fresh, sterile rinsing solution.
6. Squeeze in on the sides of the plunger before coming into contact with the lens.
7. Place the face of the plunger over the lens, and release side pressure on plunger, creating a vacuum between the plunger and the lens.
8. Release the sides of the lens, holding it with the plunger.
 - a. **IMPORTANT:** Holding the lens with the fingers while applying the plunger lessens the force against the lens. ALWAYS handle the lens by the edges when attempting to attach the plunger to the lens. **DO NOT** attach the plunger while the lens is resting on a hard surface such as a table or counter top. This will place excessive force on the lens, risking breakage. Never squeeze the sides, or place pressure on the face, of the lens.
9. **IMPROPER USE OF PLUNGER DURING LENS APPLICATION**
 - a. **DO NOT** apply force with plunger in a downward motion causing lens to break
 - b. **DO NOT** use the plunger to contact the lens while it is sitting on a hard surface
 - c. **DO NOT** attempt to take a lens out of the case with a plunger
10. Holding the plunger vertically, overfill lens with preservative-free saline, prescribed for you. Be careful to let the solution drip, not stream into the lens, in order to prevent bubbles from forming.
11. Maintain proper lid spread. Hold the eyelids at the edges, where the lashes meet the lids. The contact points should be centered on both lids, so as to form a perfectly round opening with plenty of clearance for lens application.
12. Tuck your chin to your chest. Look straight down. Keep the plunger centered in your eye by focusing on the black hole in the center of the plunger.
13. Continue approaching your eye smoothly and steadily, and stare at the black hole as if you are looking through it. Some people find it useful to shut the eye that they are not applying the lens to.
14. You will feel the fluid, but you are not there yet. Press your lens onto the eye with firm pressure.
15. Capture the lens with the eyelids by releasing the lids. Don't squint. Maintain the upward pressure on the lens while squeezing the plunger in order to release the plunger from the device.
16. The lens has now been released onto your eye! Stay squeezed while you retract the plunger away from the eye.
17. Now check your lens in the mirror. Shine a penlight onto the surface of the lens and look for the

-
- presence of any bubbles in or under the lens. If you detect bubbles the lens **MUST** be removed and reapplied.
18. Repeat the above procedure for the other eye, if applicable
 19. Clean the tip of your application plunger with warm soapy water after application of both lenses and let it air dry.

There is no single "right way" of putting on lenses. If you find this method of lens placement difficult, your eye care practitioner will suggest another method or provide additional information.

Removing the Lenses:

1. Wash and rinse your hands thoroughly
2. Dry your hands with a lint free towel
3. To avoid the possibility of lens mix-ups, always start with the same lens first.
4. Position the mirror upright on your work surface.
5. Lubricate your eye thoroughly with preservative-free saline, prescribed for you.
6. Wet a removal plunger with the preservative-free saline, prescribed for you.
7. Look straight ahead into the mirror.
8. Just as when applying your lens, execute proper lid spread. It is important to make sure the upper lid is secure during the removal to prevent scratching your eye.
9. While maintaining your lid spread, create suction with the plunger at a 45 degree angle. Aim for the 6 o'clock position on the lens, at the point where the colored portion of the eye meets the white.
10. Press the removal plunger firmly, but gently, against the device. Break the suction by tipping the bottom of the plunger up and then pull the plunger in an arc-down-and-out manner, taking care not to scratch your cornea. On some occasions, you may need to pull and relax the plunger rapidly and repeatedly. **NOTE:** If the plunger is pressed too close to the center of the lens, right over the pupil, it may not be possible to break suction and remove the lens.
11. Maintain the lid spread until the lens is out of your eye.
12. Hold the lens gently by the edges and remove the plunger from the device by twisting and maneuvering it towards the edge of the device.
13. Clean tip of your removal plunger with warm soapy water after removal of both lenses and let it air dry.

If you find this method difficult, your eye care practitioner will suggest another method or provide additional instruction.

If the lens is chipped, do not put the lens back on your eye. Return the lens to the plastic lens case and contact your eye care practitioner.

CARING FOR YOUR LENSES

Basic Instructions:

For continued safe and comfortable wearing of your **BostonSight SCLERAL** daily wear contact lenses, it is important that you **first clean and rinse** your lenses after each removal and **disinfect them daily** using the care regimen recommended by your eye care practitioner. **Cleaning and rinsing** after lens wear is 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 a 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 or have someone available to place and remove them, you should not attempt to get and wear contact lenses.

When you first get your **BostonSight SCLERAL** daily wear contact lenses, be sure you learn to comfortably put the lenses on 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 disinfection. 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 Wearer's Guide for **BostonSight SCLERAL**.

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, sterile unexpired** lens care solutions.
- * Use the recommended system of contact lens care and carefully follow instructions of your eye care provider and on solution labeling.
- * Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS.** Do not use non-compatible lens care products.
- * Do not use saliva or anything other than the recommended solutions for lubricating or rewetting contact lenses. Do not put lenses in the mouth.
- * Never rinse your contact lenses in water from the tap. There are two reasons for this:
 - a. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
 - b. You might lose the lens down the drain.
- * The eyecare practitioner should recommend a care system that is appropriate for the **BostonSight SCLERAL** daily wear contact lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.
- * **Clean** one contact lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended rinsing or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put lens into correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- * After cleaning and rinsing, **disinfect** lenses using the system recommended by the manufacturer and/or your eye care practitioner.
- * To store your contact lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, they should be removed from disinfection case, dried with a soft cloth and placed in a contact lens case dry until ready to wear. You should consult the package insert or your eye care practitioner for more information on storage of lenses.
- * **BostonSight SCLERAL** daily wear contact lenses can be disinfected using only a chemical (NOT HEAT) disinfecting system.

- * **BostonSight SCLERAL** lenses should not be worn for the minimum time required each day to disinfect the lenses.
- * Contact lens cases can be a source of bacteria growth. After removing the lenses from the case, empty and rinse the lens storage case with solution as recommended by the lens case manufacture; then allow the lens case to air dry. When the case is used again, refill it with disinfecting solution. Replace lens case at regular intervals as recommended by the lens case manufacture 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.

RECOMMENDED LENS CARE PRODUCTS

BostonSight SCLERAL daily wear contact lenses should be disinfected using only a chemical (not heat) disinfection system. The eyecare practitioner should recommend a care system that is appropriate for **BostonSight SCLERAL** daily wear contact lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed. The following lens care products are recommended (or other lens care systems as recommended by your eye care practitioner).

LENS CARE TABLE

Product Purpose	Lens Care System
Daily Cleaning	3) OPTIMUM ESC Extra Strength Cleaner (Lobob) 4) Boston [®] SIMPLUS Multi-Action Solution (Bausch & Lomb)
Cleaning, Disinfecting and Soaking.	3) OPTIMUM CDS Cleaning, Disinfecting and Storage Solution (Lobob) 4) Boston [®] SIMPLUS Multi-Action Solution (Bausch & Lomb)
Disinfecting H ₂ O ₂	3) Clear Care [®] 3% Hydrogen Peroxide Cleaning & Disinfecting Solution (Alcon) 4) Generic equivalent
Rinsing	3) PuriLens Plus Preservative Free Saline (The Lifestyle Company) 4) LacriPure Saline Solution (Menicon Co.)
Wetting & Lubricating	4) OPTIMUM GP wetting and rewetting (Lobob) 5) Boston [®] Rewetting Drops (Bausch & Lomb) 6) Refresh Plus DPS 5mg/ml (Allergan)

Specific Instructions for Use and Warnings:

a. Soaking and Storing Your Lenses

Instruction for Use:

- Use only fresh contact lens disinfecting solution each time you soak your lenses overnight.

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.

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- “Topping-Off” is the addition of fresh solution to solution that has been sitting your case.

b. Rub and Rinse Time

Instruction for Use:

- Rub and rinse your **BostonSight SCLERAL** daily wear contact lenses according to the recommended lens rubbing and rinsing times in the labeling of your daily cleaning and rinsing solutions to adequately clean your lenses.

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.

c. Lens Case Care

Instruction for Use:

- Empty and 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 rinsing or disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.
- Replace your lens case according to the directions given you by your eye care professional 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 rinsing or disinfecting 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.

d. 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. If your lenses have been submersed in water when swimming in pools, lakes or oceans, you should immediately remove them. Lenses should be cleaned and disinfected prior to re-applying. Ask your eye care practitioner (professional)

for recommendations about wearing your lenses during any activity involving water.

e. Discard Date on Contact Lens Solution Bottles

Instruction for Use:

- Discard any remaining solution after the recommended time period indicated on the bottle of contact lens solution used for cleaning, rinsing and disinfecting your contact lenses.
- The Discard date refers to the time you can safely use contact lens care product after the bottle has been opened. It is not the same as the expiration date, which is the last date that the product is still effective before it is opened.

WARNING:

- Using your contact lens solutions beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.
- To avoid contamination, DO NOT touch tip of container to any surface. Replace cap after using.
- To avoid contaminating your solution, DO NOT transfer to other bottles or containers

Chemical (NOT HEAT) Lens Disinfection:

1. Wash and rinse your hands thoroughly BEFORE HANDLING LENSES.
2. After removal of lenses, **CLEAN** the lenses by applying three drops of cleaning solution to each surface. Then rub the lens between your fingers for 20 seconds.
3. **AFTER CLEANING**, thoroughly rinse both surfaces of the lens with a steady stream of **fresh, sterile unexpired** rinsing solution for approximately 10 seconds.
4. Fill contact lens case with the recommended disinfection and storage solution and place lenses in the proper cells for the time specified in the solution label.

Note: **DO NOT HEAT THE DISINFECTION SOLUTION AND LENSES.**

Caution: Lenses that are chemically disinfected may retain ingredients from the disinfecting solution, which may be irritating to the eyes. A thorough rinse in fresh, sterile rinsing solution prior to placement on the eye should reduce the potential for irritation.

- When using hydrogen peroxide lens care systems, **the patient should use the lens case recommended by their eye care provider.** Please note the platinum catalyst from the hydrogen peroxide system must be used in order to neutralize the solution. Failure to use the platinum catalyst will result in severe stinging, burning, and injury to the eye. Following disinfection with a peroxide system, the lenses should be rinsed with sterile saline.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

The eyecare practitioner may recommend enzyme cleaning. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the wellbeing of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine daily cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

Lens Case Cleaning and Maintenance:

Contact lens cases can be a source of bacteria growth. After removing the lenses from the 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 disinfecting solution. Replace lens case at regular intervals as recommended by the lens case manufacture or your eye care practitioner.

EMERGENCIES:

If any chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, you should:

REMOVE LENSES AND FLUSH EYES IMMEDIATELY WITH TAP WATER AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

WHEN TO CALL YOUR EYECARE PRACTITIONER

Certain symptoms may be early indicators of potentially serious problems. A careful examination of your **BostonSight SCLERAL daily wear contact** lens, and professional examination of your eyes, may be required. Remove the lens following the instructions outlined in this guide, and call your eye care practitioner if:

- 1) Your eyes become red and feels irritated or "gritty".
- 2) You notice a change in your vision or see rainbows or halos around objects.
- 3) You experience discomfort and/or sensitivity to lights.

A good general policy is:

" IF IN DOUBT ... TAKE THE LENS OUT " and contact your eye care practitioner.

Learn and Use Proper lens Care Habits:

- 1) Follow Instructions.
- 2) Handle Lenses Properly.
- 3) Learn How to Apply and Remove Your Lenses.
- 4) Keep Your Lenses Clean.

5) Disinfection is a Necessary Security.

WEARING SCHEDULE:

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

Close professional supervision is necessary for therapeutic use of the **BostonSight SCLERAL** daily wear contact lenses, and patient compliance will be critical to the success of this program. Since in these cases the cornea may already be compromised, the cornea must be examined carefully and monitored continually to ensure that the device is not interfering with the condition or healing process.

The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

BostonSight SCLERAL is indicated for daily wear. The suggested wearing time for these devices is:

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

*if the lenses continue to be well-tolerated

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE BOSTONSIGHT SCLERAL DAILY WEAR CONTACT LENSES ARE SAFE TO WEAR DURING SLEEP.

APPOINTMENT SCHEDULE:

Your appointments are on:

Month	Year	Time	Day
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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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PI-002, Package Insert for BostonSight SCLERAL, Rev 2