BOSTON SIGHT

PACKAGE INSERT

BostonSight PD Prosthetic Device

FOR DAILY WEAR

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

BostonSight PD Prosthetic Device (Optimum Extra – roflufocon D) — Device Identifier: BSPDOXA

BostonSight PD Prosthetic Device (Optimum Extreme – roflufocon E) — Device Identifier: BSPDOXM

BostonSight PD Prosthetic Device (Optimum Infinite – tisilfocon A) — Device Identifier: BSPDINF

BostonSight PD Prosthetic Device (Boston Equalens II® – oprifocon A) — Device Identifier: BSPDEII

BostonSight PD Prosthetic Device (Boston XO2® – hexafocon B) — Device Identifier: BSPDXO2

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 device.

DESCRIPTION OF DEVICES

BostonSight PD Prosthetic Device is a daily wear, prosthetic device for the ocular surface 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

BostonSight PD Prosthetic Device for daily wear is designed to vault over the cornea and rest on the conjunctiva overlying the sclera, resulting in a tear reservoir between the back surface of the prosthetic device and the corneal surface. The tear reservoir masks optical distortions from an irregular corneal surface, and in combination with the device itself, protects the ocular surface from an adverse external environment, including but not limited to dysfunctional eyelids and margins. The design parameters are customized to allow for tear exchange underneath the device.

The physical properties of **BostonSight PD Prosthetic Device** are as follows:

	roflufocon D	roflufocon E	tisilfocon A	oprifocon A	hexafocon B
Refractive Index	1.4333	1.4332	1.4378	1.4230	1.4240
Light Transmission (clear)	> 97%	> 97%	n/a	> 95%	> 95%
Light Transmission (tinted)	> 90%	> 90%	> 91%	> 90%	> 83%
Water Content	< 1%	< 1%	< 1%	< 1%	< 1%
Specific Gravity	1.166	1.155	1.20	1.24	1.19
Oxygen Permeability (Dk) ISO/FATT Method	100	125	200	85	141
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, C.I. Solvent Yellow 18	D&C Green No. 6, FD & C Red No. 17, C.I. Solvent Yellow 18	D&C Green No. 6, C.I. 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

The parameters for the **BostonSight PD Prosthetic Device** are as follows:

* Chord Diameter: 12.0 mm to 26.0 mm
* Center Thickness: 0.05 mm to 0.60 mm
* Base Curve: 5.0 mm to 9.0 mm
* Spherical Powers: -25.00 Diopters to +35.00 Diopters

ACTIONS

When placed on the eye for therapeutic use, **BostonSight PD Prosthetic Device** for daily wear replaces or supports impaired ocular surface function. Additionally, BostonSight **PD Prosthetic Device** for daily wear act as a refracting media to focus light rays on the retina.

CAUTION – ***Non-sterile. Clean and condition device 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 device that can affect device 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 device performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

INDICATIONS

BostonSight PD Prosthetic Device 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).

BostonSight PD Prosthetic Device for daily wear 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, **BostonSight PD Prosthetic Device** for daily wear may concurrently provide correction of refractive error.

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

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE **BostonSight PD Prosthetic Device** for daily wear when any of the following conditions are present:

* Acute and subacute inflammation or infection of the anterior chamber of the eye.
* Post-operative patients should not be fitted with **BostonSight PD Prosthetic Device** until the determination is made that the eye has healed completely.
* 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 PD Prosthetic Device**.
* 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 PROSTHETIC DEVICE 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 the device and lens care products, including the storage 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 DEVICE** 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 prosthetic device wearers must see their eye care practitioner as directed.
* Consult your eye care practitioner regarding the use of **BostonSight PD Prosthetic Device** in certain atmospheric conditions that can cause irritation to the eye.
* **BostonSight PD Prosthetic Device** for daily wear are not indicated for overnight wear, and patients should be instructed not to wear device while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these devices 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 packaging for leakage when devices are wet shipped. If the packaging is damaged or leaking, throw away damaged packaging and replace with a new lens case and refill with new cleaning, disinfection and storage solution.

Prior to dispensing, it is important to THOROUGHLY RINSE all solution from the device since it could sting and cause irritation if instilled directly in the eye. All devices, 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 devices 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 (roflufocon D, roflufocon 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 device parameters that are presently available in this lens material.
* Consequently, when selecting an appropriate device design and parameters, the eye care practitioner should consider all characteristics of the device that can affect device 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 device 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 BostonSight **PD Prosthetic Device** for daily wear 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 devices or should have someone else available who can remove the device for him or her.
* Eye care practitioners should instruct the patient to remove the devices 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 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 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 devices.
* Always wash and rinse hands before handling devices. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the devices. It is best to apply devices before putting on makeup. Water-base cosmetics are less likely to damage devices than oil-base.
* Do not touch the devices with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the devices 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 **BostonSight PD Prosthetic Device** for daily wear and those prescribed by the eye care practitioner.
* Never wear devices beyond the period recommended by the eye care practitioner.
* Always inspect devices for chips or cracks prior to application.
* If aerosol products such as hair spray are used while wearing devices, exercise caution and keep eyes closed until the spray has settled.
* Always handle **BostonSight PD Prosthetic Device** for daily wear carefully and avoid dropping them.
* Avoid all harmful or irritating vapors and fumes while wearing devices.
* Ask the eye care practitioner about wearing **BostonSight PD Prosthetic Device** for daily wear during sporting activities.
* Inform the doctor (health care practitioner) about being a device wearer.
* Never use tweezers or other tools to remove devices from the lens case unless specifically indicated for that use. Pour the device into the hand.
* Do not touch the device 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 devices.
* 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 device 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 the patient notices any of the above, he or she should be instructed to:

* **IMMEDIATELY REMOVE BOSTONSIGHT PD PROSTHETIC DEVICE FOR DAILY WEAR**.
* If discomfort or problems stops, then look closely at the device. If the device is in any way damaged, **DO NOT PUT THE DEVICE BACK ON THE EYE.** Place the device in the storage case and contact the eye practitioner. If the device has dirt, an eyelash, or other foreign body on it, or the problem stops, and the device appears undamaged, the patient should thoroughly clean and rinse the devices, then reapply them. After re-application, if the problem continues, the patient should **IMMEDIATELY REMOVE THE DEVICES 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 DEVICES 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 devices. There is a possibility that the existing disease or condition might become worse when a prosthetic device 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 PD Prosthetic Device** should not be provided with this device. All necessary steps in device 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 PD Prosthetic Device**. A diagnostic fitting procedure is recommended, although not always required. Due to the small number of patients enrolled in clinical investigation, all refractive powers, design configurations, or parameters available in the device material were not evaluated in significant numbers.

Consequently, when selecting an appropriate design and parameters, the eye care practitioner should consider all characteristics of the device that can affect 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 device performance on the eye should be carefully monitored by the prescribing eye care practitioner.

Fitting Procedure for BostonSight PD Prosthetic Device

The basis for the **BostonSight PD Prosthetic Device** fitting system revolves around the observation that the therapeutic management of conditions such as corneal degeneration (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration), corneal dystrophy (e.g, lattice dystrophy, Reis-Bucklers dystrophy), scarring from surgery (e.g. corneal transplant, LASIK, radial keratotomy), infection, or trauma 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 device 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 PD Prosthetic Device** fluid-ventilated device 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 device 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 the prosthetic device is decreased, the area of its haptic bearing surface becomes smaller. Smaller bearing surfaces increases scleral compression. The average recommended starting diameter is 18.0 or 18.5 mm. When treating pediatric patients an average starting point is usually 17 mm. Large sizes, i.e., 19 mm are useful for large globes such as those with keratoectasia and high myopia.

Normalized Vault Value (NVV)

The internal sagittal height of a prosthetic device is determined by the radii and chord lengths of its central and peripheral posterior curves. For purposes of standardization a chord length of 15 mm intersecting a curve of 14 mm radius has been chosen as the reference base. If, for customization purposes, the posterior chord length of the optic portion is chosen to be larger or smaller than 15 mm, the calculation of the NVV is adjusted according to the theoretical model. This enables the clinician to control the corneal clearance for a given eye independent of the posterior optic zones. The recommended corneal apical clearance is 200μ to 300μ. It is preferable to err on the side of creating generous corneal clearance in order to avoid **any** apical compression after the device has settled. The goal is to achieve a corneal clearance of at least 250μ clearance over 75% of the corneal surface including the limbus in order to allow for the anticipated settling of the prosthetic device.

Base Curve

The **BostonSight PD Prosthetic Device** design decouples base curve changes from effects in corneal clearance and vault 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, devices with flatter base curves may increase the need for plus power and the resulting increased 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 device 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 devices 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 8.5 mm usually suffices – which falls within the standard base curve parameters in the **BostonSight PD Prosthetic Device** trial set. This also reduces the required minus power of these devices. Residual higher order aberrations should be suspected if the best corrected visual acuity is not accounted for by other ocular pathology. In such cases, the clinician should trial devices with aspheric optics and/or check for residual astigmatism.

Device Parameter Availability

Chord Diameter*: 12.0 mm to 26.0 mm
Center Thickness: 0.05 mm to 0.60 mm
Base Curve*: 5.0 mm to 9.0 mm
Spherical Powers: -25.00 Diopters to +35.00 Diopters
*Custom parameters available

Diagnostic Device Set

Customization starts with the use of diagnostic prosthetic devices (PD). Basic set is composed of 45-55 PD ranging from 16-23 mm diameter choices, different base curve, vault, front surface eccentricities, and power options. For irregular corneas, a typical starting point is 18.5 mm, 8.0 base curve, mid-value for front surface eccentricity, and a 2.8 mm vault. Similarly, for regular corneas, 18.5 mm, 8.0 base curve, lower-value or zero (none) front surface eccentricity, and a 2.6 mm vault. The clinician will choose next PD after assessing first PD on eye and on that basis modify suboptimal haptic and vault parameters along as many as 8 independent hemi-meridians. A representative trial set is illustrated in Figure 1.

Fitting Goals for BostonSight PD Prosthetic Device

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

1. Corneal clearance: The thickness of the fluid compartment over the corneal apex is approximately 200μ to 400μ (in comparison, the center thickness (CT) of the normal cornea is about 500μ).
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 device has been applied bubble-free.
5. The device centers well and is virtually motionless on blinking.
6. The edge of the device does not impinge on bulbar conjunctiva.
7. The imprint of the edge of the device on the bulbar conjunctiva, if present, is not sharply demarcated and does not stain with fluorescein after device removal.

Fitting Principles of the BostonSight PD Prosthetic Device

The process of fitting **BostonSight PD Prosthetic Device** is based on identifying the best fitting trial devices and adapting their geometries and power to create the eye-specific device. The steps are as follows:

1. Identify the trial device 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 from the trials set or that is specified upon ordering.
4. Repeat the process until the best fitting trial device is identified.
5. Perform over-refraction to determine optimum optical power and asphericity.
6. Order the prosthetic device.
   Note: The eye-specific design may be a composite of the parameters of several trial devices.
7. Repeat the cycle with the ordered device.

Figure 1.

Vault (mm)	Power (D)	Diameter (mm)	Base Curve (mm)	Front Surface Eccentricity
4.20	0.5	18.0	7.90	None
4.35	8.50	18.0	7.80	Mid Value
4.40	-1.75	18.5	7.90	None
4.40	0.0	17.0	7.90	None
4.40	0.0	18.0	7.90	None
4.40	2.75	18.0	7.90	High Value
4.40	0.0	18.0	7.90	None
4.40	-3.0	18.0	7.90	Low Value
4.50	-2.0	21.0	7.90	None
4.50	-3.0	18.5	7.90	Mid Value
4.50	-1.0	18.5	7.90	None
4.50	1.0	21.0	7.89	High Value
4.50	1.0	18.5	7.90	None
4.50	-8.1	18.0	8.60	None
4.50	-0.25	17.0	7.90	None
4.50	5.5	18.0	7.80	None
4.60	0.0	18.5	7.90	None
4.60	-2.0	16.0	7.90	None
4.60	-2.25	18.5	7.90	None
4.65	-3.75	18.0	8.60	Mid Value
4.65	-0.25	18.5	8.60	None
4.65	-4.0	18.0	8.60	None
4.65	0.75	19.0	7.90	Low Value
4.65	0.75	19.0	7.90	None
4.65	1.0	18.5	7.90	None
4.65	1.0	18.5	7.90	None
4.65	1.0	19.0	7.90	None
4.70	0.25	23.0	8.40	None
4.70	12.25	18.5	7.90	Mid Value
4.70	12.25	18.5	7.90	High Value
4.70	12.25	18.5	7.90	None
4.80	-1.0	23.0	7.90	None
4.80	-3.0	18.5	7.20	None
4.85	0.0	19.5	7.90	None
4.85	-0.25	19.5	7.90	Mid Value
4.85	0.0	19.5	7.90	None
4.85	-2.0	16.0	7.90	None
4.85	0.25	19.5	7.90	None
4.90	1.0	19.0	7.90	Low Value
5.00	1.0	16.0	7.90	None
5.00	0.75	16.5	7.90	None
5.00	0.0	16.5	7.90	None
5.00	1.25	15.5	7.90	None
5.00	0.75	16.0	7.90	None
5.00	1.25	16.0	7.90	None
5.10	3.25	20.0	7.90	None
5.20	0.75	20.0	7.90	None
5.20	0.75	20.0	7.90	Mid Value
5.30	0.0	19.5	7.90	None
5.30	-0.25	19.5	7.90	None
5.40	-5.5	20.0	7.20	Low Value
5.40	-5.75	20.0	7.20	Mid Value
5.90	0.5	22.0	7.20	High Value
5.90	-2.75	20.0	7.20	High Value

Fitting the BostonSight PD Prosthetic Device with Topography

Selection for a **BostonSight PD Prosthetic Device** can be aided by the use central corneal curvature clues derived from keratometry reading or Sim K obtained from video keratography.

Determining Power

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

Fitting Tips

*When ordering the **BostonSight PD Prosthetic Device** specify the:

1. Eye
2. Diameter
3. Vault
4. Haptic radius
5. Base Curve
6. Power
7. Eccentricity

Troubleshooting

PD Suction/Adhesion:

Symptoms of this phenomenon include discomfort, bulbar conjunctival injection and delayed onset of misty vision. These symptoms increase with wearing time and persist for a significant period after PD removal.

Slit lamp evaluation will reveal corneal epithelial edema and injection of the limbal conjunctiva. Difficulty in PD removal is also associated with this phenomenon. This is by far one of the most common causes of limited tolerance. Increasing corneal clearance might be called for vaults that are too shallow or marginal. Flattening the haptic radius will allow for improved scleral alignment in case of an impinging PD and resolve suction. Similarly increasing the diameter will allow for a weight distribution over a larger surface area and avoid harsh compression which could lead to suction.

If excessive suction persists despite the above efforts, haptic fenestrations and/or channels may be helpful. As a last resort, peripheral optic fenestrations may be required.

Post Lasik and RK eyes:

It is preferable to choose flatter base curves (i.e. 8.5 mm) in order to clear the intermediate corneal bulge and avoid requiring high minus device 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 device removal to replace the fluid in the reservoir. The use of more viscous fluid in the reservoir, such as preservative-free Refresh Celluvisc, can delay the accumulation of debris under the device.

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

a. Re-evaluating the toricity of the individual haptic meridian,
b. Decreasing the 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 device:

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) or similar, followed by a saline rinse or in some instances just by removing the devices and simply rubbing their surfaces with preservative-free saline. Alternatively, to minimize coating. it is possible to add a post-manufacturing, FDA-approved, hydrophilic coating, if applicable per doctor's recommendation.

Hooding of the limbal bulbar conjunctiva:

Loose bulbar conjunctiva is often seen overlapping the peripheral cornea during 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 device, fluid has been imbibed under this tissue **and** there is significant resistance to device removal, excessive 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 device compression over the corneal periphery. This can be resolved by a flatter base curve and, if indicated, increasing the sagittal height.

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

a. Residual hydrogen peroxide. This is always associated with stinging on device insertion and may indicate the need for more a more complete saline rinse prior to 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 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 device is removed.

Device-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 wetting solutions if used for 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 diameter.
b. Raised pinguecula and pterygia: The choice of diameter is determined by the distance of the lesion from the limbus. If it is located more peripherally, smaller diameters can be considered if they **do not impinge on the lesion**. More often it is necessary to increase the 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.

Device awareness/discomfort:

In the absence of 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 edge, bevel or diameter.

Blurred vision that develops after device application:

Common causes include:

a. Deposits accumulating on the front surface of the device.
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 after device removal and the patient's observation of rainbows around light sources.

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

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

Discrete round or oval depression of the corneal surface present immediately after 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 wear.

Rippled texture of the corneal surface immediately after 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 dispensing
* After three weeks of wear
* After seven weeks of wear
* After each six-month period of wear.

At the follow-up examinations, the patient should report good subjective quality of vision. Adaptation to vision of the **BostonSight PD Prosthetic Device** should occur almost immediately and should 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 prosthetic device in place.
2. Over refract to verify device prescription.
3. Observe the position of the device on the eye. The device 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 device. 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. Reinsert the device only after all residual Fluorescein has dissipated from the eye.
7. Clean the device with a prophylactic surfactant cleaner, and examine for deposits, foreign bodies or physical imperfections of the surface.

Device 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 device while in the eye using lubricating and rewetting drops before removal.* Always start with the right prosthetic device first in order to avoid mixing the devices. In removing the devices, try to avoid touching the inside (concave) surface. After removing the device from its container assure that it is clean, clear and wet.

In-Office Cleaning, Disinfecting and Storage

When packaged wet the **BostonSight PD Prosthetic Device** received in the eye care practitioner's office is received non-sterile in an individual plastic container and labeled as to the parameters of the device contained. When the prosthetic devices 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 device since it will sting and cause irritation if instilled directly in the eye. After rinsing is complete and prior to inserting into patients' eye, apply 2 drops of wetting and rewetting drops to each surface of the device WITHOUT rubbing the device. Repeat the procedure with the other device.

When packaged dry, the **BostonSight PD Prosthetic Device** received in the eye care practitioner's office is received Non-sterile in an individual plastic container and labeled as to the parameters of the device contained. The device should be cleaned, rinsed and disinfected using a chemical (not heat) disinfection system prior to dispensing to the patient. Reference the cleaning section for procedures for cleaning.

Storage

The **BostonSight PD Prosthetic Device** must always be stored in the individual plastic container with the recommended solutions. If exposed to the air, damage could be caused to the device.

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 **BostonSight PD Prosthetic Device** for daily wear, 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 PD Prosthetic Device are 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 BOSTONSIGHT PD PROSTHETIC DEVICE FOR DAILY WEAR ARE SAFE TO WEAR DURING SLEEP.

PROSTHETIC DEVICE CARE DIRECTIONS

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

* **Basic Instructions:**

Care of the prosthetic device 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 the prosthetic device. 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 devices. Do not put devices in the mouth. Devices should be **cleaned, rinsed, and disinfected** daily. **Cleaning and rinsing** are necessary to remove mucus and film from the device 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) devices 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 Devices**

Instruction for Use:

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

WARNING:

- Do not reuse or "top off" old solution left in the lens case since solution reuse reduces effective device 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 devices according to the recommended lens rubbing and rinsing times in the labeling of the multi-purpose or daily cleaning solution to adequately clean the devices.
- Soak the devices 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 devices for the recommended amount of time to help prevent serious eye infections.
- Never use water, saline solution, or rewetting drops to disinfect the devices. These solutions will not disinfect the devices. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

c. **Lens Case Care**

Instruction for Use:

- Empty and clean 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.
- Lens cases can be a source of bacterial growth.

WARNING:

- Do not rinse the devices 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 devices 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 devices to water while wearing them.

WARNING:

- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the devices have been submersed in water when swimming in pools, lakes or oceans, the patient should **IMMEDIATELY REMOVE THEM**. Devices should be cleaned and disinfected prior to re-applying. The patient should ask the eye care practitioner (professional) for recommendations about wearing the devices 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 lens solution.
- The Discard date refers to the time the patient can safely use 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 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.

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

Clean one **BostonSight PD Prosthetic Device** for daily wear first (always the same device first to avoid mix-ups), rinse the device thoroughly with recommended rinsing solution to remove the cleaning solution, mucus, and film from the device surface, and put device into correct chamber of the device disinfection case. Then repeat the procedure for the second device. After cleaning and rinsing, **disinfect** devices using the system recommended by the manufacture and/or the eye care practitioner. To store device, remove from disinfection case, dry with a soft towel and store dry in a screw-top contact lens case until ready to wear. **BostonSight PD Prosthetic Device** should not be worn for the minimum time required each day to disinfect the lenses.

* **Device Care Regimen:**

Patients must adhere to the device care regimen recommended by their eye care practitioner for the care of **BostonSight PD Prosthetic Device** for daily wear. Failure to follow this procedure may result in development of serious ocular infections

* **Storage:**

BostonSight PD Prosthetic Device for daily wear must be stored dry in an individual plastic case.

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

1. Wash and rinse your hands thoroughly BEFORE HANDLING DEVICES.
2. After removal of devices, **CLEAN** the devices 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 device thoroughly with a steady stream of **fresh, sterile unexpired** rinsing solution for approximately 10 seconds.
4. Fill the lens case with the recommended disinfection solution and place devices in the proper cells for the time specified on the solution label.

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

Caution: Devices 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 devices 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 by your eye care professional.

RECOMMENDED LENS CARE PRODUCTS

BostonSight PD Prosthetic Device for daily wear should be disinfected using only a chemical (not heat) disinfection system. The eyecare practitioner should recommend a care system that is appropriate **BostonSight PD Prosthetic Device**. 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) Boston® SIMPLUS Multi-Action Solution (Bausch & Lomb, Inc.; Medical Device License (MDL): 102533) 2) Generic equivalent
Cleaning, Disinfecting and Soaking.	1) Boston® SIMPLUS Multi-Action Solution (Bausch & Lomb, Inc.; MDL: 102533) 2) Generic equivalent
Disinfecting H_2O_2	1) Alcon Clear Care Cleaning and Disinfection Solution 3% Hydrogen Peroxide (Alcon Canada, Inc.; Drug Identification Number (DIN): 02245661) 2) Generic equivalent
Rinsing	1) PuriLens Plus Preservative Free Saline (The Lifestyle Company, Inc.; MDL: 99969) 2) Lacripure Saline Solution (Menicon Co., LTD; MDL:100054
Wetting & Lubricating	1) Refresh Plus DPS 5mg/ml (Allergan, Inc.; DIN: 02049260) 2) Generic equivalent

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

HOW SUPPLIED:

BostonSight PD Prosthetic Device for daily wear may be shipped "dry" or "wet" in a polypropylene contact lens case. The primary container for shipping **BostonSight PD Prosthetic Device** for daily wear is the Bausch & Lomb Frequent Replacement Contact Lens Case.

When shipped "wet", **BostonSight PD Prosthetic Device** for daily wear are shipped in 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 Package Inserts are available from:

BostonSight
464 Hillside Avenue
Suite 205
Needham, MA 02494
USA
(781) 726-7337
www.bostonsight.org

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

Manufactured By:
BostonSight
464 Hillside Avenue
Suite 205
Needham, MA 02494
USA
(781) 726-7337

BOSTON SIGHT

PATIENT INSTRUCTION / WEARER'S GUIDE

BostonSight PD Prosthetic Device

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 PD Prosthetic Device** for daily wear. 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: _____

Parameters	TYPE	POWER	DIAM.	BC	LOT#
Right					
Left					

Disinfection Solution: _____

Rinsing Solution: _____

Daily Cleaner: _____

Lubricating Solution: _____

INTRODUCTION:

Your **BostonSight PD Prosthetic Device** for daily wear is 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 PD Prosthetic Device** for daily wear 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 PD Prosthetic Device** for daily wear. If you are in doubt about any instructions, request clarification from your eye care practitioner.

WEARING RESTRICTIONS and INDICATIONS:

Indication for Use:

BostonSight PD Prosthetic Device 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).

BostonSight PD Prosthetic Device for daily wear 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, **BostonSight PD Prosthetic Device** for daily wear may concurrently provide correction of refractive error.

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

DO NOT WEAR **BostonSight PD Prosthetic Device** for daily wear WHILE SLEEPING.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE **BostonSight PD Prosthetic Device** for daily wear when any of the following conditions are present:

* Acute and subacute inflammation or infection of the anterior chamber of the eye.
* Post-operative patients should not be fitted with **BostonSight PD Prosthetic Device** until the determination is made that the eye has healed completely.
* 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 PD Prosthetic Device**.
* 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 PROSTHETIC DEVICE 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 the device and lens care products, including the storage 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 DEVICE** 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 prosthetic device wearers must see their eye care practitioner as directed.
* Consult your eye care practitioner regarding the use of **BostonSight PD Prosthetic Device** in certain atmospheric conditions that can cause irritation to the eye.
* **BostonSight PD Prosthetic Device** for daily wear are not indicated for overnight wear, and patients should be instructed not to wear device while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these devices 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 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 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 devices.
* Always wash and rinse hands before handling devices. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the devices. It is best to apply devices before putting on makeup. Water-base cosmetics are less likely to damage devices than oil-base.
* Do not touch the devices with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the devices 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 **BostonSight PD Prosthetic Device** for daily wear and those prescribed by the eye care practitioner.
* Never wear devices beyond the period recommended by the eye care practitioner.
* Always inspect devices for chips or cracks prior to application.
* If aerosol products such as hair spray are used while wearing devices, exercise caution and keep eyes closed until the spray has settled.
* Always handle **BostonSight PD Prosthetic Device** for daily wear carefully and avoid dropping them.
* Avoid all harmful or irritating vapors and fumes while wearing devices.
* Ask the eye care practitioner about wearing **BostonSight PD Prosthetic Device** for daily wear during sporting activities.
* Inform the doctor (health care practitioner) about being a device wearer.
* Never use tweezers or other tools to remove devices from the lens case unless specifically indicated for that use. Pour the device into the hand.
* Do not touch the device 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 devices.
* 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 following problems may occur:

* Eyes stinging, burning, itching (irritation), or other eye pain.
* Comfort is less than when device 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 DEVICES**.

* If discomfort or problems stops, then look closely at the device. If the device is in any way damaged, **DO NOT PUT THE DEVICE BACK ON YOUR EYE.** Place the device in the storage case and contact your eye practitioner. If the device has dirt, an eyelash, or other foreign body on it, or the problem stops and the device appears undamaged, you should thoroughly clean and rinse, the devices before reapplying them. After reapplication, if the problem continues, you should **IMMEDIATELY REMOVE THE DEVICES 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 DEVICE 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 devices. There is a possibility that the existing disease or condition might become worse when a contact device 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 DEVICE HANDLING

Before Handling Your devices:

Cleanliness is an important aspect of device care.

Before handling your **BostonSight PD Prosthetic Device** for daily wear, 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 devices. When hair spray is used, the eye must be kept closed until the spray has settled. Take care in handling your devices.

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

NEVER WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE DEVICE 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 device(s). 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 Devices 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 device mix-ups, always start with the same device first.
4. Empty the contents of the case (i.e. the device) into the palm of your hand. With the other hand, GENTLY grasp the device by the edges. Note: the device should be wet during this process.
5. Before applying the device, rinse well with fresh, sterile rinsing solution.
6. Squeeze in on the sides of the plunger before coming into contact with the device.
7. Place the face of the plunger over the device, and release side pressure on plunger, creating a vacuum between the plunger and the device.
8. Release the sides of the device, holding it with the plunger.
   a. **IMPORTANT:** Holding the device with the fingers while applying the plunger lessens the force against the device. ALWAYS handle the device by the edges when attempting to attach the plunger to the device. **DO NOT** attach the plunger while the device is resting on a hard surface such as a table or counter top. This will place excessive force on the device, risking breakage. Never squeeze the sides, or place pressure on the face, of the device.
9. **IMPROPER USE OF PLUNGER DURING DEVICE APPLICATION**
   a. DO NOT apply force with plunger in a downward motion causing device to break.
   b. DO NOT use the plunger to contact the device while it is sitting on a hard surface.
   c. DO NOT attempt to take a device out of the case with a plunger.
10. Holding the plunger vertically, overfill device with preservative-free saline, prescribed for you. Be careful to let the solution drip, not stream into the device, 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 device 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 device to.
14. You will feel the fluid, but you are not there yet. Press your device onto the eye with firm pressure.
15. Capture the device with the eyelids by releasing the lids. Don't squint. Maintain the upward pressure on the device while squeezing the plunger in order to release the plunger from the device.
16. The device has now been released onto your eye! Stay squeezed while you retract the plunger away from the eye.
17. Now check your device in the mirror. Shine a penlight onto the surface of the device and look for the presence of any bubbles in or under the device. If you detect bubbles the device **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 devices and let it air dry.

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

Removing the Devices:

1. Wash and rinse your hands thoroughly.
2. Dry your hands with a lint free towel.
3. To avoid the possibility of device mix-ups, always start with the same device 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 device, 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 device, 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 device, right over the pupil, it may not be possible to break suction and remove the device.
11. Maintain the lid spread until the device is out of your eye.
12. Hold the device 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 devices 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 device is chipped, do not put the device back on your eye. Return the device to the plastic lens case and contact your eye care practitioner.

CARING FOR YOUR DEVICES

Basic Instructions:

For continued safe and comfortable wearing of your **BostonSight PD Prosthetic Device** for daily wear, it is important that you **first clean and rinse** your devices after each removal and **disinfect them daily** using the care regimen recommended by your eye care practitioner. **Cleaning and rinsing** after device wear is necessary to remove mucus, secretions, films, or deposits which may have accumulated during wear. The ideal time to clean your devices 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 devices or are unable to place and remove devices or have someone available to place and remove them, you should not attempt to get and wear contact devices.

When you first get your **BostonSight PD Prosthetic Device** for daily wear, be sure you learn to comfortably put the devices 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 device care, handling, cleaning, and disinfection. Your eye care practitioner should instruct you about appropriate and adequate procedures and products for your use.

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

* Always wash, rinse, and dry hands before handling contact devices.
* Always use **fresh, sterile unexpired** lens care solutions.
* Use the recommended system of device 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 devices. **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 devices. Do not put devices in the mouth.
* Never rinse your devices in water from the tap. There are two reasons for this:
   a. Tap water contains many impurities that can contaminate or damage your devices and may lead to eye infection or injury.
   b. You might lose the device down the drain.
* The eyecare practitioner should recommend a care system that is appropriate for BostonSight **PD Prosthetic Device** for daily wear. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.
* **Clean** one contact device first (always the same device first to avoid mix-ups), rinse the device thoroughly with recommended rinsing or disinfecting solution to remove the cleaning solution, mucus, and film from the device surface, and put device into correct chamber of the device storage case. Then repeat the procedure for the second device.
* After cleaning and rinsing, **disinfect** devices using the system recommended by the manufacturer and/or your eye care practitioner.
* To store your devices, disinfect and leave them in the closed/unopened case until ready to wear. If devices are not to be used immediately following disinfection, they should be removed from disinfection case, dried with a soft cloth and placed in a lens case dry until ready to wear. You should consult the package insert or your eye care practitioner for more information on storage of devices.
* **BostonSight PD Prosthetic Device** for daily wear can be disinfected using only a chemical (NOT HEAT) disinfecting system.
* **BostonSight PD Prosthetic Device** should not be worn for the minimum time required each day to disinfect the lenses.
* Lens cases can be a source of bacteria growth. After removing the devices 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 devices while you are wearing them to make them more comfortable.

RECOMMENDED LENS CARE PRODUCTS

BostonSight PD Prosthetic Device for daily wear should be disinfected using only a chemical (not heat) disinfection system. The eyecare practitioner should recommend a care system that is appropriate **BostonSight PD Prosthetic Device**. 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) Boston® SIMPLUS Multi-Action Solution (Bausch & Lomb, Inc.; Medical Device License (MDL): 102533) 2) Generic equivalent
Cleaning, Disinfecting and Soaking.	1) Boston® SIMPLUS Multi-Action Solution (Bausch & Lomb, Inc.; MDL: 102533) 2) Generic equivalent
Disinfecting H_2O_2	1) Alcon Clear Care Cleaning and Disinfection Solution 3% Hydrogen Peroxide (Alcon Canada, Inc.; Drug Identification Number (DIN): 02245661) 2) Generic equivalent
Rinsing	1) PuriLens Plus Preservative Free Saline (The Lifestyle Company, Inc.; MDL: 99969) 2) Lacripure Saline Solution (Menicon Co., LTD; MDL:100054
Wetting & Lubricating	1) Refresh Plus DPS 5mg/ml (Allergan, Inc.; DIN: 02049260) 2) Generic equivalent

Specific Instructions for Use and Warnings:

a. **Soaking and Storing Your Devices**

Instruction for Use:

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

WARNING:

- Do not reuse or "top off" old solution left in your lens case since solution reuse reduces effective device 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 your case.

b. **Rub and Rinse Time**

Instruction for Use:

- Rub and rinse your **BostonSight PD Prosthetic Device** for daily wear according to the recommended device rubbing and rinsing times in the labeling of your daily cleaning and rinsing solutions to adequately clean your devices.

WARNING:

- Rub and rinse your devices for the recommended amount of time to help prevent serious eye infections.
- Never use water, saline solution, or rewetting drops to disinfect your devices. These solutions will not disinfect your devices. 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.
- Lens cases can be a source of bacterial growth.

WARNING:

- Do not store your devices 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 devices 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 devices to water while you are wearing them.

WARNING:

- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your devices have been submersed in water when swimming in pools, lakes or oceans, you should immediately remove them. Devices should be cleaned and disinfected prior to re-applying. Ask your eye care practitioner (professional) for recommendations about wearing your devices during any activity involving water.

e. **Discard Date on Lens Solution Bottles**

Instruction for Use:

- Discard any remaining solution after the recommended time period indicated on the bottle of lens solution used for cleaning, rinsing and disinfecting your devices.
- The Discard date refers to the time you can safely use 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) Device Disinfection:

1. Wash and rinse your hands thoroughly BEFORE HANDLING DEVICES.
2. After removal of devices, **CLEAN** the devices by applying three drops of cleaning solution to each surface. Then rub the device between your fingers for 20 seconds.
3. AFTER CLEANING, thoroughly rinse both surfaces of the device 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 devices in the proper cells for the time specified in the solution label.

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

Caution: Devices 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 devices should be rinsed with sterile saline.

DEVICE DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

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

Lens cases can be a source of bacteria growth. After removing the devices 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 DEVICES 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 PD Prosthetic Device** for daily wear, and professional examination of your eyes, may be required. Remove the device 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 DEVICE OUT" and contact your eye care practitioner.

Learn and Use Proper device Care Habits:

1) Follow Instructions.
2) Handle Devices Properly.
3) Learn How to Apply and Remove Your Devices.
4) Keep Your Devices 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 BostonSight **PD Prosthetic Device** for daily wear, 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 PD Prosthetic Device are 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 BOSTONSIGHT PD PROSTHETIC DEVICE FOR DAILY WEAR ARE SAFE TO WEAR DURING SLEEP.

APPOINTMENT SCHEDULE:

Your appointments are on:

Month Year Time Day

_____

IMPORTANT:

In the event that you experience any difficulty wearing your devices 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-004, Package Insert for BostonSight PD Prosthetic Device_CN, Rev 1