

PACKAGE INSERT



BOSTON SIGHT

BostonSight IC Corneal & Scleral Lenses

For

DAILY WEAR

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

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IMPORTANT

Please read carefully and keep this information for future use. This package insert is intended for the eye care practitioner, but should be made available to the patient upon request. The eye care practitioner should provide the patient with the wearer's guide that pertains to the patients prescribed lens.

DESCRIPTION OF LENSES

The **BostonSight Irregular Cornea (IC) Corneal & Scleral Lenses** are lathe cut and fabricated from one of the following hydrophobic rigid gas permeable (RGP) lens materials:

- OPTIMUM EXTRA (rofluvocon D) supplied by Contamac Ltd.
- OPTIMUM EXTREME (rofluvocon E) supplied by Contamac Ltd.
- BOSTON EQUALENS II (oprifocon A) supplied by Bausch and Lomb, Inc.

- BOSTON XO₂ (hexafocon B) supplied by Bausch and Lomb, Inc.

The description of the OPTIMUM EXTRA & EXTREME, BOSTON EQUALENS II, and BOSTON XO₂ RGP materials are addressed in K033594, K022128, and K071266 respectively.

The **BostonSight IC Corneal & Scleral Lenses** for daily wear may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or following refractive (e.g. LASIK) surgery.

The **BostonSight IC Scleral Lens** is a large diameter RGP lens design that vaults over the cornea and rests on the conjunctiva overlying the sclera.

The **BostonSight IC Corneal & Scleral Lenses** may be shipped “dry” or “wet” in a polypropylene contact lens case. The primary container for shipping the **BostonSight IC Corneal & Scleral Lenses** is the Bausch & Lomb Frequent Replacement Contact Lens Case, with clearance under 510(k) K896685. When shipped “wet”, The **BostonSight IC Corneal & Scleral Lenses** manufactured from material supplied by Bausch & Lomb, Inc. may be packaged and shipped in Boston Advance Comfort Formula Conditioning Solution (K974466) or Boston SIMPLUS Multi-Action solution (K024289). The **BostonSight IC Corneal & Scleral Lenses** manufactured from material supplied by Contamac, Ltd. may be packaged and shipped “wet” in in the OPTIMUM by Lobob Cleaning and Disinfecting Storage solution, with clearance under 510(k) K014162.

The physical properties of the **BostonSight IC Corneal & Scleral Lenses** manufactured from the various materials are as follows:

	OPTIMUM EXTRA (roflufocon D)	OPTIMUM EXTREME (roflufocon E)	BOSTON EQUALENS II (oprifocon A)	BOSTON XO₂ (hexafocon B)
Refractive Index	1.4333	1.4332	1.4230	1.4240
Light Transmission (clear)	>97%	>97%	>95%	>95%
Light Transmission (tinted)	>90%	>90%	>90%	>90%
Specific Gravity	1.166	1.155	1.24	1.19
Oxygen Permeability (Dk) ISO/FATT Method	100 x 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35 C)	125 x 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35 C)	85 x 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35 C)	141 x 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35 C)
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; C.I. Solvent Yellow No. 18; D&C Violet No. 2; D&C Red No. 17; C.I. Solvent Yellow No.18	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

Lens parameters:

* Chord Diameter:	8.0 mm to 26.0 mm
* Center Thickness:	0.05mm 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 ocular surface, the **BostonSight IC Corneal & Scleral Lenses** act as a refracting media to focus light rays on the retina.

CAUTION

CAUTION – Non-sterile. Clean 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 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 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 eye care practitioner.

INDICATIONS

The **BostonSight IC Corneal & Scleral Lenses** for daily wear are indicated for the correction of refractive error in aphakic and non-aphakic persons. The lenses may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (LASIK) surgery.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the **BostonSight IC Corneal & Scleral Lenses** when any of the following conditions are present:

- * Acute and subacute inflammation or infection of the anterior chamber of the eye.

- * Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- * Aphakic patients should not be fitted with **BostonSight IC Corneal & Scleral Lenses** until the determination is made that the eye has healed completely.
- * Severe insufficiency of lacrimal secretion (dry eyes).
- * Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.
- * Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- * Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- * Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for **BostonSight IC Corneal & Scleral Lenses**.
- * 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

- * **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 LENSES AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.**
- * All contact lens wearers must see their eye care practitioner as directed.
- * Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these 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 container and refill with new cleaning, disinfection and storage solution.

Prior to dispensing lenses that have been shipped wet, it is important to **THOROUGHLY RINSE** all solution from the lens 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 lens **WITHOUT** rubbing the lens.

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 (roflufocon D, roflufocon E, 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 IC Corneal & Scleral 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 promptly 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 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 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 lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base.
- * 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 IC Corneal & Scleral Lenses** and those prescribed by the eye care practitioner.
- * Never wear lenses beyond the period recommended by the eye care practitioner.
- * If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- * Always handle lenses carefully and avoid dropping.
- * Avoid all harmful or irritating vapors and fumes while wearing lenses.
- * Ask the eye care practitioner about wearing 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 container 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 LENSES.**
- * 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 lens, then apply them. After 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.

FITTING

For a detailed description of the fitting techniques, refer to **BostonSight IC Corneal & Scleral Lenses Professional Fitting and Information Guide**, copies of which are available from:

Boston Foundation for Sight
464 Hillside Avenue, Suite 205
Needham, MA 02494
781-726-7503

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WEARING SCHEDULE

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER. Patients tend to over wear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, are also extremely important.

The maximum suggested wearing schedule for the **BostonSight IC Corneal & Scleral Lenses** is reflected below.

<u>DAY</u>	<u>HOURS</u>
1	3
2	4
3	5
4	6
5	7
6	8
7	9
8	10
9	11
10 – 14	12
15+	All waking hours

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE BOSTONSIGHT IC CORNEAL & SCLERAL LENSES ARE SAFE TO WEAR DURING SLEEP.

WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

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 INDICATED ON SOLUTION LABELING.**

Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth. Lenses should be **cleaned, rinsed, and disinfected** each day. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs. The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfection solution prior to disinfecting the lenses. Eye care practitioners may recommend a lubricating/rewetting solution, which can be used to 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. Soaking and Storing the Lenses

Instruction for Use:

- Use only fresh (contact lens disinfecting) solution each time the lenses are soaked (stored).

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 and Rinse Time

Instruction for Use:

- Rub and rinse the prosthetic device according to the recommended rubbing and rinsing times to adequately disinfect the device.

WARNING:

- Rub and rinse 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 case with fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. 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.
- Contact lens cases can be a source of bacterial growth.

WARNING:

- Do not store the lenses or rinse the lens case with water or any non-sterile solution. Only use fresh 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 remove, clean and disinfect the lenses. The patient should ask the eye care practitioner (professional) for recommendations about wearing the lenses during any activity involving water.

e. Discard Date on Solution Bottle Instruction for Use:

- Discard any remaining solution after the recommended time period indicated on the bottle of solution used for disinfecting and soaking the contact lenses.
- 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 the solution 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 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 storage 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, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye care practitioner for information on storage of lenses.

* **Lens Care Regimen:**

Patients must adhere to the lens care regimen recommended by their eye care practitioner for the care of **BostonSight IC Corneal & Scleral Lenses**. Failure to follow this procedure may result in development of serious ocular infections

* **Storage:**

The **BostonSight IC Corneal & Scleral Lenses** must be stored in the individual plastic case and in the recommended solutions.

* **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 with a steady stream of **fresh, sterile unexpired** rinsing solution for approximately 10 seconds.
4. Fill the 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 absorb 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 must use ONLY the lens cleaning case for large diameter lenses. The case that comes with the hydrogen peroxide system is too small to accommodate the devices.** Failure to use the specialized case may result in a broken lens. The catalyst from the hydrogen peroxide system must be placed into the lens case to neutralize the hydrogen peroxide. Failure to use a catalyst in the cleaning case will cause severe stinging, burning, and injury to the eye. Following disinfection with a peroxide system, the devices should be rinsed with fresh, preservative-free 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 well-being 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 SOLUTIONS

BostonSight IC Corneal & Scleral Lenses should be disinfected using only a chemical (not heat) disinfection system. The following lens care systems are recommended (or other lens care systems as recommended by your eye care practitioner).

SYSTEM PROCESS	CHEMICAL (not heat) DISINFECTION SYSTEM
Daily Cleaning	<ol style="list-style-type: none"> 1) Lobob OPTIMUM RGP extra strength cleaner 2) Walgreens brand Extra Strength Daily Cleaner for soft contact lenses
Rinsing	<ol style="list-style-type: none"> 1) PuriLens Plus Saline Preservative Free 2) Sodium Chloride (NaCl) 0.9% for nebulization 3) Bausch & Lomb Sensitive Eyes Plus saline (prior to disinfection only)
Disinfecting H ₂ O ₂	<ol style="list-style-type: none"> 1) Clear Care 3% Hydrogen Peroxide Cleaning and Disinfection Solution.
Cleaning, Disinfecting and Soaking	<ol style="list-style-type: none"> 1) Clear Care 3% Hydrogen Peroxide Cleaning and Disinfection Solution.
Enzyme	<ol style="list-style-type: none"> 1) Boston One Step 2) Ultrazyme
Wetting & Lubricating	<ol style="list-style-type: none"> 1) Preservative-Free artificial tears 2) Boston® Rewetting Drops

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:

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 IC Corneal & Scleral Lenses** may be shipped “dry” or “wet” in a polypropylene contact lens case. The primary container for shipping the **BostonSight IC Corneal & Scleral Lenses** is the Bausch & Lomb Frequent Replacement Contact Lens Case, with clearance under 510(k) K896685.

When shipped “wet”, The **BostonSight IC Corneal & Scleral Lenses** manufactured from material supplied by Bausch & Lomb, Inc. may be packaged and shipped in Boston Advance Comfort Formula Conditioning Solution (K974466) or Boston SIMPLUS Multi-Action solution (K024289).

The **BostonSight IC Corneal & Scleral Lenses** manufactured from material supplied by Contamac, Ltd. may be packaged and shipped “wet” in in the OPTIMUM by Lobob Cleaning and Disinfecting Storage solution, with clearance under 510(k) K014162.

The case, packing slip and invoice are marked with the base curve, dioptic power, diameter, center thickness, color, lot number and the initial packaging date.

REPORTING OF ADVERSE REACTIONS:

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

Boston Foundation for Sight
464 Hillside Avenue, Suite 205
Needham, MA 02494
781-726-7503

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Manufactured By:
Boston Foundation for Sight
464 Hillside Avenue, Suite 205
Needham, MA 02494
781-726-7503

RELEASE DATE: 04/2017, Rev. 1

PATIENT INSTRUCTION / WEARER'S GUIDE



BOSTON SIGHT

BostonSight IC Corneal & Scleral Lenses

For

DAILY WEAR

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CONGRATULATIONS:

You have just received your new **BostonSight IC Corneal & Scleral 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: _____

Enzymatic Cleaner: _____

INTRODUCTION:

With your decision to wear the **BostonSight IC Corneal & Scleral Lenses**, you have joined a growing number of people who are discovering new pleasures from this important advance in vision for patients.

Your **BostonSight IC Corneal & Scleral 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 IC Corneal & Scleral 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 IC Corneal & Scleral Lenses**. If you are in doubt about any instructions, request clarification from your eye care practitioner.

WEARING RESTRICTIONS and INDICATIONS:

Indication for Use:

The **BostonSight IC Corneal & Scleral Lenses** for daily wear are indicated for the correction of refractive error in aphakic and non-aphakic persons. The lenses may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive LASIK) surgery.

The **BostonSight IC Corneal & Scleral Lenses** described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eye care practitioner.

DO NOT WEAR BostonSight IC Corneal & Scleral Lenses WHILE SLEEPING.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the BostonSight IC Corneal & Scleral Lenses when any of the following conditions exist:

- * Acute and subacute inflammation or infection of the anterior chamber of the eye.

- * Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- * Aphakic patients should not be fitted with **BostonSight IC Corneal & Scleral Lenses** until the determination is made that the eye has healed completely.
- * Severe insufficiency of lacrimal secretion (dry eyes).
- * Corneal hypoesthesia (reduced corneal sensitivity), if non-aphakic.
- * Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- * Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- * Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the **BostonSight IC Corneal & Scleral Lenses**.
- * Any active corneal infection (bacterial, fungal, or viral)
- * If eyes become red or irritated.
- * You are unable to follow the lens care regimen or unable to obtain assistance to do so.

WARNINGS:

- * **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 LENSES AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.**
- * You must see your eye care practitioner as directed.
- * Daily wear lenses are not indicated for overnight wear, and you are instructed not to wear the **BostonSight IC Corneal & Scleral Lenses** while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- * Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

PRECAUTIONS:

- * **CAUTION – Non-sterile.** Clean 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 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 lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base.
- * 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 IC Corneal & Scleral Lenses** and those prescribed by the eye care practitioner.
- * Never wear lenses beyond the period recommended by the eye care practitioner.
- * If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- * Always handle lenses carefully and avoid dropping them.
- * Avoid all harmful or irritating vapors and fumes while wearing lenses.
- * Ask the eye care practitioner about wearing 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 container 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 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 LENS.**
- * Look closely at the lens. If the lens is in 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: then re-apply them. After re-application, 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.

PERSONAL CLEANLINESS and LENS HANDLING

Before handling your lenses:

Cleanliness is an important aspect of contact lens care.

Before handling your 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. Always avoid touching your lenses with your fingernails or other sharp objects. **NEVER WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE LENS MAY BE LOST.**

Handling and applying the lens on the eye:

- 1) To avoid the possibility of mix-ups, always start with the same device first (right or

- left).
- 4) Before applying the device, rinse well with fresh, preservative-free saline solution. While handling your device by the edges, place the device on the application plunger while gently squeezing the plunger to produce suction.
 - 5) While keeping the plunger vertical, overfill the device with preservative-free saline that has been opened less than 48 hours.
 - 6) 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.
 - 7) Tuck your chin to your chest. Look straight down into the center of the plunger and bring the plunger to the eye. Press the device onto the eye with firm pressure.
 - 8) 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.
 - 9) Check your device in the mirror by shining 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.
 - 10) Repeat the above procedure for the second device. 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 prosthetic devices. If you find this method of placement difficult, your eye care practitioner will suggest another method or provide additional information.

Removing the device:

Preparation:

- 1) Wash and rinse your hands thoroughly.
- 2) Dry hands with a lint-free towel.
- 3) You will need a removal plunger, a small mirror positioned upright and preservative-free saline prescribed for you.

Removal:

- 1) To avoid the possibility of mix-ups, always begin with the same device (right or left).
- 2) Position a mirror upright on your work surface.
- 3) Lubricate your eye thoroughly with preservative-free saline, prescribed for you.
- 4) Wet a removal plunger with the preservative-free saline, prescribed for you.
- 5) Look straight ahead into the mirror.
- 6) 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 removal. It is important to make sure the upper lid is secure during the removal to prevent scratching your eye.
- 7) 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. 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.

- 8) Maintain the lid spread until the device is out of your eye.
- 9) 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.
- 10) Repeat the procedure for the second eye.
- 11) Clean tip of your removal plunger with warm soapy water after removal of both devices and let it air dry.
- 12) If the device cannot be easily moved, apply a few drops of preservative-free saline to the eye, blink a few times, and wet the plunger again before attempting removal again. If the device still cannot be removed, contact your eye care practitioner for further instruction.
- 13) Upon removal, clean each prosthetic device with a lens cleaner per the procedures described under the heading, CARING FOR YOUR DEVICE. Rinse well with sterile saline solution and place in the storage case filled with fresh disinfection solution.

IMPORTANT: Always avoid touching your device with your fingernails. Use only your fingertips. If you find this method difficult, your eye care practitioner will suggest another method or provide additional instruction.

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

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

CARING FOR YOUR LENSES

Basic Instructions:

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

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

- * Always wash, rinse, and dry hands before handling contact lenses.
- * Always use **fresh, sterile unexpired** lens care solutions.
- * Use the recommended system of lens care and carefully follow instructions on solution labeling.
- * Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING.**
- * Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- * Never rinse your lenses in water from the tap. There are two reasons for this:
 - a. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
 - b. You might lose the lens down the drain.
- * The eyecare practitioner should recommend a care system that is appropriate for the **BostonSight IC Corneal & Scleral Lenses**. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.
- * **Clean** one 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 manufacture and/or your eye care practitioner.
- * To store lens, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, you should consult the package insert or your eye care practitioner for information on storage of lenses.
- * If you discontinue wearing your lenses, but plan to begin wearing them after a few weeks, ask your eye care practitioner for a recommendation on how to store your lenses.
- * **BostonSight IC Corneal & Scleral Lenses** can be disinfected using only a

chemical (NOT HEAT) disinfecting system.

- * 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 storage 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.

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 (store) your lenses.

WARNING:

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

b. Rub and Rinse Time Instruction

for Use:

- Rub and rinse your lenses according to the recommended lens rubbing and rinsing times in the labeling of your solution to adequately disinfect 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 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 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 discard them and replace them with a new pair. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

e. Discard Date on Solution Bottle Instruction

for Use:

- Discard any remaining solution after the recommended time period indicated on the bottle of solution used for disinfecting and soaking your contact lenses.
- 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 solution 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 15 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 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 absorb 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 must use ONLY the lens cleaning case for large diameter lenses. The case that comes with the hydrogen peroxide system is too small to accommodate the devices.** Failure to use the specialized case may result in a broken lens. The catalyst from the hydrogen peroxide system must be placed into the lens case to neutralize the hydrogen peroxide. Failure to use a catalyst in the cleaning case will cause severe stinging, burning, and injury to the eye. Following disinfection with a peroxide system, the devices should be rinsed with fresh, preservative-free 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 well-being 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:

FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY 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 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 eye becomes 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 YOUR EYE CARE PRACTITIONER.

The maximum suggested wearing schedule for the **BostonSight IC Corneal & Scleral Lenses** is reflected below.

<u>DAY</u>	<u>HOURS</u>
1	3
2	4
3	5
4	6
15	7
16	8
17	9
18	10
19	11
10 – 14	12
15+	All waking hours

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE BostonSight IC Corneal & Scleral Lenses IS SAFE TO WEAR DURING SLEEP.

WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

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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