BostonSight®

PRACTITIONER INSTRUCTIONS FOR USE

BostonSight® Specialty Lenses

(roflufocon D, roflufocon E, tisilfocon A, hexafocon B, oprifocon A, fluoroxyfocon A)

Gas Permeable Contact Lenses for Daily Wear

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

Multifocal Contact Lenses for Presbyopia

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

Spherical, Aspherical & Multifocal Scleral Lenses for Myopia, Hyperopia, Ocular Surface Disease, and Irregular Corneal Conditions

℞ ONLY

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

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

IMPORTANT

Please read carefully and keep this information for future use. This Practitioner Instructions for Use 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 Patient Information Booklet that pertains to the patient's prescribed lens.

DESCRIPTION

BostonSight® Specialty Lenses for daily wear are lathe cut from one of the following hydrophobic, FDA Group #3 fluoro-silicone acrylate rigid gas permeable (RGP) lens materials:

- roflufocon D supplied by Contamac Ltd.
- roflufocon E supplied by Contamac Ltd.
- tisilfocon A supplied by Contamac Ltd.
- hexafocon B supplied by Bausch & Lomb, Inc.
- oprifocon A supplied by Bausch & Lomb, Inc.
- fluoroxyfocon A supplied by Acuity Polymers, Inc.

BostonSight Specialty Lenses for daily wear fabricated from roflufocon D, roflufocon E, tisilfocon A, hexafocon B, fluoroxyfocon A are available with or without Tangible® Hydra-PEG, which is a thin polyethylene glycol (PEG)-based polymer that is covalently bonded to the surface of the contact lens and is designed to enhance the surface properties of the contact lens while retaining the mechanical and optical properties of the underlying material. BostonSight Specialty Lenses for daily wear fabricated from oprifocon A are not available with Tangible® Hydra-PEG.

BostonSight Specialty Lenses for daily wear may be shipped dry or wet in a polypropylene contact lens case. The primary container for shipping BostonSight Specialty Lenses for daily wear is the Bausch & Lomb "US Lens Case W&B" (K013232). When shipped wet, BostonSight Specialty Lenses for daily wear are packaged non-sterile in Boston SIMPLUS® Multi-Action solution (K024289).

The physical properties of BostonSight Specialty Lenses for daily wear are as follows:

	roflufocon D	roflufocon E	tisilfocon A	oprifocon A	hexafocon B	fluoroxyfocon A
Refractive Index	1.4333	1.4332	1.4378	1.4230	1.4240	1.430
Light Transmission (clear)	>97%	>97%	-	>95%	>95%	-
Light Transmission (tinted)	>90%	>90%	>91%	>90%	>83%	>87%
Water Content	<1%	<1%	<1%	<1%	<1%	<1%
Specific Gravity	1.166	1.155	1.20	1.24	1.19	1.18
Oxygen Permeability (Dk) ISO/FATT Method	100 x 10^{-11} (cm2/sec) (ml O2/ml x mm Hg @ 35°C)	125 x 10^{-11} (cm2/sec) (ml O2/ml x mm Hg @ 35°C	180 x 10^{-11} (cm2/sec) (ml O2/ml x mm Hg @ 35°C)	85 x 10^{-11} (cm2/sec) (ml O2/ml x mm Hg @ 35°C)	141 x 10^{-11} (cm2/sec) (ml O2/ml x mm Hg @ 35°C)	200 x 10^{-11} (cm2/sec) (ml O2/ml x mm Hg @ 35°C)
Contain one or more of the following color additives conforming to: 21 CFR Part 73 & 74, Subpart D	D&C Green No. 6, D&C Red No. 17, C.I. Solvent Yellow 18	D&C Green No. 6, D&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, D&C Red No. 17	D&C Green No.6, D&C Yellow No.18	D&C Green No. 6, C.I. Solvent Yellow No. 18, D&C Violet No. 2, D&C Red No. 17	D&C Green No. 6, D&C Violet No. 2, Solvent Yellow 18, D&C Red No. 17
UV Light Blocking	Yes	Yes	Yes	Yes	Yes	Yes
Dynamic Receding Contact Angle	3°	6°	-	56°	40°	-
Tangible® Hydra-PEG Available	Yes	Yes	Yes	No	Yes	Yes

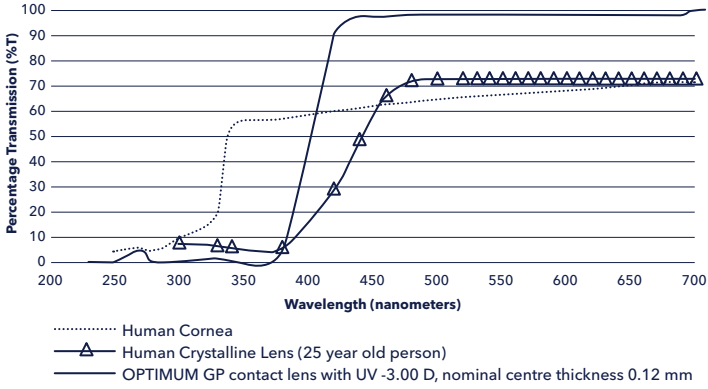
BostonSight Specialty Lenses for daily wear are available in the following lens parameters:

Parameter	Range	Tolerance
Base Curve	5.00 mm to 11.50 mm	± 0.05 mm
Center Thickness	0.05 mm to 0.75 mm	± 0.02 mm
Chord Diameter	7.00 mm to 26.00 mm	± 0.10 mm
Spherical Power	-25.00 D to +35.00 D (in 0.25 D steps)	± 0.12 (0 to </= 5 D) ± 0.18 (5 to </= 10.0 D) ± 0.25 (10 to </= 15 D) ± 0.37 (15 to </= 20 D) ± 0.50 (over 20 D)
Cylindrical Power	Up to -10.00 D (in 0.25 D steps)	± 0.25 (0 to </= 2 D) ± 0.37 (2 to </= 4 D) ± 0.50 (over 4 D)
Cylindrical Axis	1° to 180° (in 1° steps)	± 5°
Multifocal Power	+1.00 D to 4.00 D (in 0.25 D steps)	± 0.25 D

In BostonSight Specialty Lenses for daily wear manufactured from roflufocon D and E with UV Blocker, a Benzophenone UV blocker is used to block UV radiation. The UV Blocker is 2, 2'-Dihydroxy-4, 4' dimethoxybenzophenone. The UV-blocking for roflufocon D and E averages > 98% in the UVB range (280nm – 315nm) and 95% in the UVA range (316nm – 380nm).

The following graph compares the UV transmittance profile of the -3.00 D roflufocon D and E Contact Lens with UV to that of a cornea and crystalline lens. Data was obtained from measurements taken through the central 3-5 mm portion of the thinnest marketed version of the UV lens. Typical Transmittance Profile of -3.00 D OPTIMUM GP Contact Lens with UV versus a Human Cornea and Human Lens.

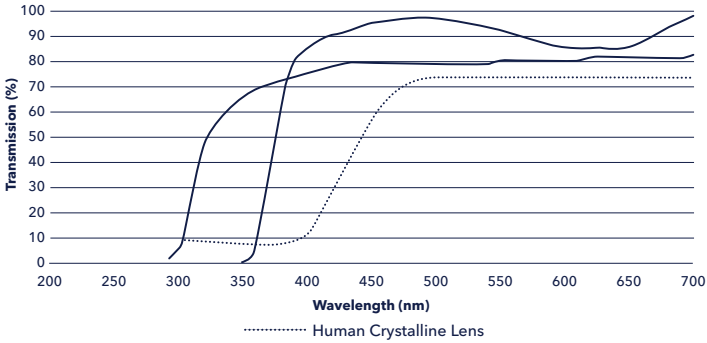
Typical Transmittance Profile of -3.00 D roflufocon D and E (Optimum GP) Contact Lenses with UV versus a Human Cornea and Human Lens.



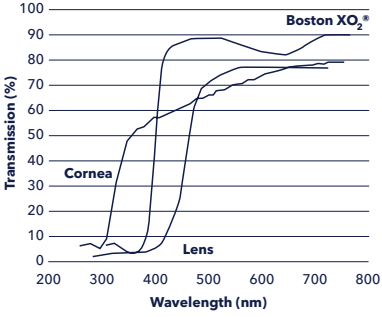
In BostonSight Specialty Lenses for daily wear manufactured from tisilfocon A with UV Blocker, a Benzophenone UV blocking monomer is used to block >99% of UV radiation in the UVB range (280nm – 315nm) and >85% in the UVA range (316 – 380nm).

The following graph compares the UV transmittance profile of the tisilfocon A with Benzophenone UV blocking monomer, –3.00 D & .06mm thick, to that of a cornea and crystalline lens. Data was obtained from measurements taken through the central 3-5mm portion of the thinnest marketed version of the UV lens.

Light transmitteance profile of Tisilfocon A Blue/UV versus a Human Cornea and Human Lens

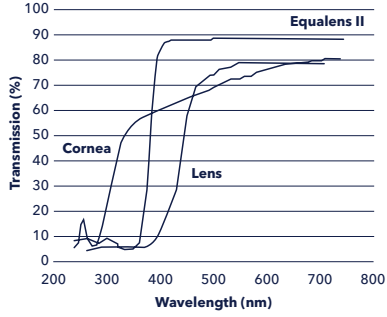


In BostonSight Specialty Lenses for daily wear manufactured from hexafocon A with UV absorber (Uvinul D-49 or MHB)



Boston XO$_2$® - 0.07 mm thick
Boston XO$_2$® Contact Lens/Material (Ice Blue)

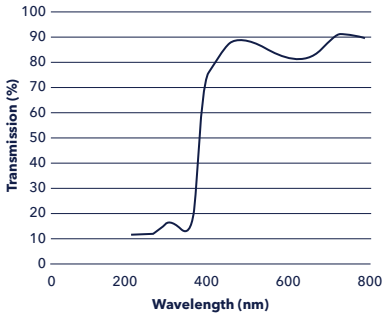
In BostonSight Specialty Lenses for daily wear manufactured from oprifocon A with UV absorber (Uvinul D-49 or MHB).



Boston® Equalens® II - 0.07 mm thick Boston® Equalens® II (Clear) Contact Lens/Material

In BostonSight Specialty Lenses for daily wear manufactured from flluoroxyfococn UV absorber

% Transmission Acuity 200(fluoroxyfocon A) Blue with UV Absorber



Acuity 200- 0.15 mm thick Acuity 200 (Blue)

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

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

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

WARNING

UV-absorbing contact lenses are **not** substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. Patients should be instructed to continue to use their protective UV-absorbing eyewear as directed.

ACTIONS

BostonSight Specialty Lenses Lenses (roflufocon D, roflufocon E, tisilfocon A, hexafocon B, oprifocon A, fluoroxyfocon A) for daily wear act as a refracting media to focus light rays on the retina. When placed on the eye for therapeutic use, BostonSight Specialty Lenses for daily wear in the scleral lens designs replace or support impaired ocular surface function.

Practitioner Note: BostonSight Specialty Lenses for daily wear are not sterile when shipped. Prior to dispensing, clean and condition the lens(es) according to the appropriate lens care regimen.

INDICATIONS (USES)

BostonSight Specialty Lenses (roflufocon D, roflufocon E, tisilfocon A, hexafocon B, oprifocon A, fluoroxyfocon A) for daily wear are indicated for the correction of refractive ametropia (myopia, hyperopia, astigmatism, and presbyopia) in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be prescribed in otherwise non-diseased eyes that require a gas permeable contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive surgery.

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

BostonSight Specialty Lenses for daily wear in the scleral lens designs are 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.

Additionally, BostonSight Specialty Lenses for daily wear in the scleral lens designs are indicated for therapeutic use for the management of irregular and distorted corneal surfaces. 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). When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the BostonSight Specialty Scleral Lenses for daily wear may concurrently provide correction of refractive error.

Eye care practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

CONTRAINDICATIONS (REASON NOT TO USE)

DO NOT USE BostonSight Specialty Lenses (roflufocon D, roflufocon E, tisilfocon A, hexafocon B, oprifocon A, fluoroxyfocon A) for daily wear 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, other than irregular corneal conditions as described in the INDICATIONS section, that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes) except when using a scleral lens design that maintains a fluid chamber between the cornea/conjunctiva and the contact lens.
- Corneal hypoesthesia (reduced corneal sensitivity), except when using a scleral lens design that maintains a fluid chamber between the cornea/conjunctiva and the contact lens and acts as a protective barrier for the cornea if non-aphakic.
- Any systemic disease that may affect the eye and would be exaggerated by wearing the lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or using contact lens care solutions
- Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for BostonSight Specialty Lenses for daily wear
- 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

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

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that patients follow their eye care practitioner's 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.
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these daily wear lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- All contact lens wearers must see their eye care practitioner as directed.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove lenses and promptly contact their eye care practitioner.**

PRECAUTIONS

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

Never reuse the solution. You may store the lenses in the unopened container until ready to dispense, up to a maximum of thirty days from the date of manufacture (see lens shipping pouch label). If the lenses are stored for longer periods of time, they should be cleaned and disinfected using the recommended solutions.

All lenses, whether shipped wet or dry, should be cleaned with daily cleaner and rinsed with unexpired rinsing solution prior to applying to the patient's eye.

Special Precautions for Eye Care Practitioner:

- When shipped wet, BostonSight Specialty Lenses for daily wear are packaged non-sterile in Boston SIMPLUS® Multi-Action Solution, a sterile, aqueous, buffered solution that contains poloxamine, hydroxyalky phosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with polyaminopropyl biguanide (0.0005%), chlorhexidine gluconate (0.003%). If the patient has experienced a prior history of allergy to any of the ingredients in Boston SIMPLUS® Multi-Action Solution, remove the lens from the solution and soak the lens 24 hours in fresh, unexpired, preservative-free saline solution prior to cleaning, disinfecting, and dispensing.
- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction. The continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

- Patients who wear contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Aphakic patients should not be fitted with BostonSight Specialty Lenses for daily wear until the determination is made that the eye is completely healed.
- Before leaving the eye care practitioner's office, the patient should be able to properly remove lenses or should have someone else available who can remove the lenses for them.
- Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- The presence of the UV light absorber in the contact lens materials may require equipment enhancement to visualize fluorescein patterns adequately.

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.
- Do not heat the conditioning/ storage solution and/or lenses. Keep them away from extreme heat.
- Always use **unexpired** lens care solutions.
- Always follow directions in the Package Inserts for the use of contact lens solutions.
- Sterile preservative-free solutions should be discarded after the time specified in the labeling directions
- Do not use saliva, water, or anything other than the recommended solution for lubricating or rewetting lenses.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp BostonSight Specialty Lenses for daily wear.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, more than 30 days, they must first be cleaned, rinsed with fresh, unexpired, preservative-free saline solution, disinfected and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. These lenses should be cleaned and disinfected prior to application.
- BostonSight Specialty Lenses for daily wear with Tangible® Hydra-PEG must be stored in the lens storage case with the recommended solution. Dry storage is not recommended.
- If the lens sticks (stops moving) on the eye, the patient should be instructed to apply 1 to 3 drops of the recommended rewetting (lubricating) solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 15 minutes, the patient should **immediately consult their eye care practitioner**. This action does not apply to scleral lens designs.
- Always wash hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, application, removal, cleaning,

disinfecting, storing, and wearing instructions in the Patient Information Booklet for BostonSight Specialty Lenses and those provided by the eye care practitioner.

- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Patients should be advised about wearing lenses during sporting and water-related activities.
- Patients should be instructed to not expose contact lenses to water while wearing them. Water can harbor microorganisms that can lead to severe infection, vision loss, or blindness. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection including but not limited to Acanthamoeba keratitis. If lenses have been submersed in water, they should be immediately removed, thoroughly cleaned, and disinfected before reapplication.
- Instruct patient to inform their doctor (health care practitioner) that they are a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. To remove the lens from the case, pour the lens into the palm of your hand.
- Do not touch the lens with fingernails.
- Instruct the patient to contact their eye care practitioner before using any medicine in their eyes.
- Instruct the patient to inform their employer that they wear contact lenses. Some jobs may require the use of eye protection equipment or may require that the patient not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Patients with limbal stem cell deficiency may need to be monitored more closely to prevent progression of the disease, and if any progression of the disease is noted, contact lens wear may have to be reduced or terminated.

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) 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 lenses.**
- If the discomfort or problem stops, look closely at the lens. If the lens is in any way damaged, **do not put the lens back on the eye**. Place the lens in the lens case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lens, then

reapply it. After reapplication, if the problem continues, the patient should **immediately remove the lens and consult their eye care practitioner**.

- When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to **keep the lens off the eye and seek immediate professional identification** of the problem and prompt treatment to avoid serious eye damage.
- During use for the management of irregular corneal conditions, an adverse effect may be due to the original condition or may be due to the effect of wearing a contact lens. There is a possibility that the existing disease or condition might become worse when a contact lens is used to treat an already diseased or damaged eye. The patient should be instructed to avoid serious eye damage by contacting their eye care practitioner **IMMEDIATELY** if there is any increase in symptoms while wearing the lens.

FITTING

Conventional methods of fitting rigid gas permeable lenses apply to BostonSight Specialty Lenses for daily wear. For a detailed description of the fitting techniques, refer to BostonSight Specialty Lenses for daily wear *Fitting and Information Guides*, copies of which are available from:

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

WEARING SCHEDULE

The wearing and replacement schedule 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. BostonSight Specialty Lenses are indicated for daily wear.

Close professional supervision is necessary for therapeutic use of BostonSight Specialty Lenses 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.

LENS CARE DIRECTIONS

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

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

General Lens Care Information

- Contact lens care requires three essential steps – **cleaning, rinsing, and disinfection.**
- Each step in the lens care process is important and one step is not to be replaced by the other.
- Always wash hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before handling the contact lenses.
- Always use **unexpired** lens care solutions.
- Use the recommended chemical (not heat) lens care system 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, or if advised by the eye care practitioner.

- Do not use saliva, water, or anything other than the recommended solutions for lubricating or wetting lenses.
- Do not put lenses in the mouth.
- Lenses should be **cleaned, rinsed, and disinfected** daily after use.
- **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface.
- **Disinfecting** is necessary to destroy harmful germs.
- 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.

Specific Instructions for Use and Warnings:

1. Clean and Rinse

Instruction for Use:

- Follow the complete recommended lens rubbing and rinsing times in the labeling of your multi-purpose or daily cleaning solution to adequately clean your lenses and reduce the risk of contact lens infection.
- **Always clean** one lens at a time in the same order to avoid mix-ups. Rinse the lens thoroughly with the recommended rinsing solution to remove the cleaning solution, mucus, and film from the lens surface. Place the lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

WARNING:

- Rub and rinse your lenses for the recommended amount of time to help prevent serious eye infections.

2. Disinfect and Store

Use the recommended chemical (not heat) disinfection lens care system and carefully follow instructions on solution labeling.

Instruction for Use:

- Lenses must be clean and rinsed prior to disinfecting.
- Use only unexpired contact lens disinfecting solution each time you disinfect or store your lenses.
- Fill the clean, dry contact lens case with unexpired recommended storage and disinfection solution and place lenses in the proper chambers for the time specified on the solution label.
- **DO NOT HEAT THE DISINFECTION SOLUTION AND LENSES.**
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, instruct the patient to consult their eye care practitioner for information on storing their lenses.
- If dry storage is desired to store the lenses for a longer period of time, more than 30 days, they must first be cleaned, rinsed with fresh, unexpired, preservative-free saline solution, disinfected, and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. These lenses should be cleaned and disinfected prior to application.
- BostonSight Specialty Lenses for daily wear with Tangible® Hydra-PEG must be stored in the lens storage case with the recommended solution. Dry storage is not recommended.

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 in the case.
- Soak the lenses in the contact lens disinfecting solution according to the labeling instructions to allow

completion of the disinfection process. Removing before minimum soak time will result in incomplete disinfection and possible eye irritation or injury.

- **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.
- Lenses that are chemically disinfected may retain ingredients from the disinfecting solution, which may be irritating to the eyes. A thorough rinse in fresh, unexpired, preservative-free saline solution prior to placement on the eye should reduce the potential for irritation.

3. Lens Deposits and Use of Enzymatic Cleaning

- Enzymatic cleaning may be recommended by the eye care practitioner to effectively remove protein deposits from 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.
- Enzymatic cleaning does NOT replace routine daily cleaning and disinfecting. For enzymatic cleaning, instruct the patient to carefully follow the instructions in the enzymatic cleaning labeling.
- Enzymatic cleaner is NOT recommended for use with lenses coated with Tangible® Hydra-PEG.

4. Lens Case Care

Instruction for Use:

- The lens case must be emptied after each use, cleaned, and dried.
- Clean contact lens case with digital rubbing using sterile disinfecting solutions/contact lens cleaner. **Never use water.** Cleaning should be followed by rinsing with fresh disinfecting solutions **(never use water)** and wiping the lens case with a fresh, clean tissue. 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 labeling that came with the case, or the directions given by the eye care practitioner.

WARNING:

- Contact lens cases can be a source of bacterial growth.
- Do not store your 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.

5. Discard Date on Contact Lens Solution Bottle

Instruction for Use:

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

WARNING:

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

RECOMMENDED LENS CARE PRODUCTS

BostonSight Specialty Lenses should be disinfected using only a chemical (not heat) disinfection system. The eye care practitioner should recommend a care system that is appropriate for BostonSight Specialty Lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

The lens care products listed below are recommended by BostonSight for use with BostonSight Specialty Lenses for daily wear. Eye care practitioners may recommend alternative products that are appropriate for the patient's use with their lenses.

Lens Care Table for BostonSight Specialty Lenses

Product Purpose	Lens Care System
Clean	• Boston SIMPLUS® Multi-Action Solution • Menicon Unique pH® Multi-Purpose Solution
Rinse	• Sterile, preservative-free saline solution as recommended by eye care practitioner
Disinfect	• Boston SIMPLUS® Multi-Action Solution • Menicon Unique pH® Multi-Purpose Solution • Alcon Clear Care® Cleaning and Disinfection Solution
Store	• Boston SIMPLUS® Multi-Action Solution • Menicon Unique pH® Multi-Purpose Solution
Rewet/ Lubricate	• Boston® Rewetting Drops • Sterile, preservative-free saline solution as recommended by eye care practitioner
Use with scleral lenses	• Sterile, preservative-free saline solution as recommended by eye care practitioner

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.

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, THEN REMOVE LENSES PROMPTLY, IF POSSIBLE, AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

To aid with conditioning, BostonSight Specialty Lenses for daily wear are packaged non-sterile in a plastic lens storage case filled with Boston SIMPLUS® Multi-Action Solution, a sterile, aqueous, buffered solution that contains poloxamine, hydroxyalky phosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with polyaminopropyl biguanide (0.0005%), chlorhexidine gluconate (0.003%). Boston SIMPLUS® Multi-Action Solution is a cleaning, disinfecting and conditioning product that has an added protein remover.

The solution needs to be replaced with fresh, sterile, unexpired solution within 30 days from the manufacture date indicated on the device label. If the patient has experienced a prior history of allergy to any of the ingredients in Boston SIMPLUS® Multi-Action Solution, remove the lens from the solution and soak the lens 24 hours in fresh, unexpired, preservative-free saline solution prior to cleaning, disinfecting, and dispensing.

Additional information on Boston SIMPLUS® Multi-Action Solution is available at *www.bausch.com/ecp/our-products/contact-lens-care/gas-permeable-lens-care/boston-simplus-solution* including the package insert, which contains the solution composition as well as important safety and use information.

The lens package is labeled with the base curve, diopter power, diameter, center thickness, color, and lot number. Additional parameters may be included to identify lens design options selected by the eye care practitioner.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing BostonSight Specialty Lenses should be reported to the manufacturer:

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