PACKAGE INSERT

BAUSCH + LOMB

Zenlens® scleral lenses

Gas Permeable Contact Lenses for Daily Wear

Zenlens®
Catalog No. **AOZNS**
(Boston XO® – hexafocon A, Boston XO_2® – hexafocon B)
(Optimum Extra – roflufocon D, Optimum Extreme – roflufocon E)

Zenlens® Multifocal
Catalog No. **AOZMS**
(Boston XO® – hexafocon A, Boston XO_2® – hexafocon B)
(Optimum Extra – roflufocon D, Optimum Extreme – roflufocon E)

Zenlens® Toric
Catalog No. **AOZNT**
(Boston XO® – hexafocon A, Boston XO_2® – hexafocon B)
(Optimum Extra – roflufocon D, Optimum Extreme – roflufocon E)

Zenlens® with Tangible® Hydra-PEG®
Catalog No. **AOZNS**
(Boston XO® – hexafocon A, Boston XO_2® – hexafocon B)

Zenlens® Multifocal with Tangible® Hydra-PEG®
Catalog No. **AOZMS**
(Boston XO® – hexafocon A, Boston XO_2® – hexafocon B)

Zenlens® Toric with Tangible® Hydra-PEG®
Catalog No. **AOZNT**
(Boston XO® – hexafocon A, Boston XO_2® – hexafocon B)

Rev. 2022-10 8216200

℞ ONLY **CAUTION:** Federal (USA) Law restricts this device to sale by or on the order of a licensed eye care practitioner.

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 patient's prescribed lens.

DESCRIPTION

Zenlens® and Zenlens® with Tangible® Hydra-PEG® Contact Lenses are manufactured using Boston XO® (hexafocon A), which is a gas permeable contact lens material composed of siloxanyl fluoromethacrylate copolymer. The Boston XO® material contains an ultraviolet absorber (MHB).

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

The Zenlens® with Tangible® Hydra-PEG® Contact Lenses are treated to incorporate Hydra-PEG Technology (HPT) – which is a thin polyethylene glycol (PEG)-based polymer that is covalently (permanently) bonded to the surface of the contact lens and is designed to enhance the surface properties of the contact lens while retaining the mechanical properties of the underlying material. When treated with HPT, the underlying material (hexafocon A and B) is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (dynamic contact receding angle) compared to untreated lenses. The resulting layer is hydrophilic and approximately 30nm in thickness.

The Boston XO® and Boston XO_2® contact lens material is supplied by Bausch & Lomb Incorporated.

The contact lenses are hemispherical shells of the following standard dimensions:

- Sagittal Depth Range: 3.200 to 6.700
- Chord Diameter: 14.8 mm, 15.4 mm, 16.0 mm and 17.0 mm
- Spherical Powers: (spherical lenses) -20.00 D to +20.00 D
- Spherical Powers: (toric lenses) -20.00 D to +20.00 D
- Cylinder Powers: (toric lenses) -0.50 D to -9.00 D
- Axis: (toric lenses) 1° to 180°
- Add Power: (multifocal) +1.00 D to +3.75 D
- Add Zone Diameter: (multifocal) 1.5 mm to 3.5 mm
- Near Optic Decentration: (multifocal) Zero to 1.0 mm
- Optical Axis: (multifocal) 1° to 360°
- Advanced Peripheral System (APS)
  Steep-10 to Steep-1, Standard, Flat+1 to Flat+20
  (Available in 30 micron increments)
- Options: Toric Peripheral Curves (APS)
  Flexure Control Profile
  Custom Center Thickness
  Front Toric Rx
  MicroVault

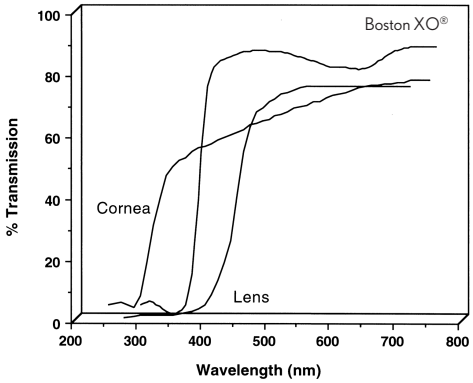
Physical/Optical Properties of Zenlens® and Zenlens® with Tangible® Hydra-PEG® Contact Lenses manufactured with Boston XO® Material:

The tinted lenses contain the following color additives:

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

Specific Gravity:	1.27	
Refractive Index:	1.415	
Light Absorbance:	(640nm) 7.8	Blue
Light Absorbance:	(640nm) 5.4	Ice Blue
Light Absorbance:	(585nm) 5.4	Violet
Light Absorbance: (Absorbance units/inch)	(640nm) 4.9	Green
Light Transmittance*:	92% *Average %T (400nm - 800nm)	
Surface Character:	Hydrophobic	
Wetting Angle:	49°	
Wetting Angle w/ Hydra-PEG:	10°	
Water Content:	<1%	
Oxygen Permeability:	140* (100**)	

{Dk Units = 10^{-11} (cm^3O_2 • cm) / (cm^2 • sec • mmHg) @ 35°C}
* Gas to gas method
**Polarographic method (ISO/Fatt)



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

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

The tinted lenses contain the following color additives:

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

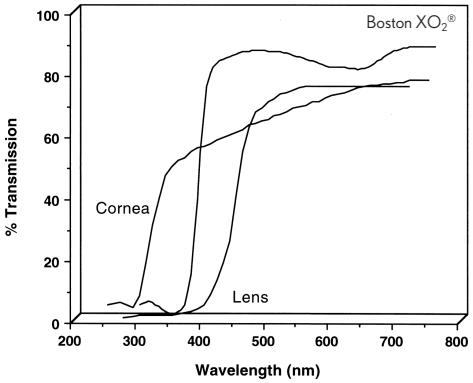
Specific Gravity:	1.19
Refractive Index:	1.424
Light Transmittance*:	

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

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

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

{Dk Units = 10^{-11} (cm^3O_2 • cm) / (cm^2 • sec • mmHg) @ 35°C}
**Polarographic method (ISO/Fatt)



Boston XO_2® - 0.07 mm thick Boston XO_2® Contact Lens/Material (Ice Blue)

NOTE
Long-term exposure to 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.

DESCRIPTION OF LENSES

Zenlens® Contact Lens manufactured using the **OPTIMUM GP** (roflufocon D and E) for Daily Wear is a rigid gas permeable methacrylate copolymer of Methyl methacrylate, 1,1,1,3,3,3 - Hexafluoroisopropyl Methacrylate, Methacryloxypropyl Tris(trimethylsiloxy) silane, 1,3-bis (methacryloxypropyl)-1,1,3,3-tetrakis (trimethyl siloxy) disiloxane, 2-Hydroxyethyl Methacrylate, and Methacrylic acrylic acid cross-linked with Ethylene Glycol Dimethacrylate.

The **OPTIMUM GP** (roflufocon D and E) Contact Lens for Daily Wear incorporates a visibility tint to make the lens more visible for handling.

The tinted lenses contain one or more of the following color additives: D&C Green No. 6, C.I. Solvent Yellow No. 18, and FD&C Red No. 17.

The physical properties of the **OPTIMUM GP** are:

Physical Property	roflufocon D	roflufocon E
Refractive Index	1.4333	1.4332
Light Transmission (clear)	>97%	>97%
Light Transmission (tinted)	>90%	>90%
Wetting Angle (Dynamic contact receding angle)	3°	6°
Specific Gravity	1.166	1.155
Oxygen Permeability (Dk) ISO/FATT Method	100	125
Visitint lenses contain more than one of the following color additives	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

UV Blocker

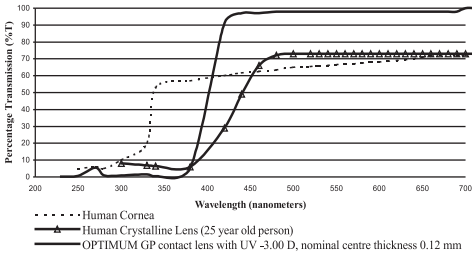
In the OPTIMUM GP (roflufocon D and E) Contact Lens for Daily Wear with UV Blocker, a Benzophenone UV blocker is used to block UV radiation. The UV Blocker is 2, 2'-Dihydroxy-4, 4' dimethoxybenzophenone. The UV-blocking for OPTIMUM GP averages > 98% in the UVB range of 280nm – 315nm and 95% in the UVA range of 316nm – 380nm.

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

Long-term exposure to 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.

The following graph compares the UV transmittance profile of the -3.00 D **OPTIMUM GP** 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



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.

ACTIONS

Zenlens® and Zenlens® with Tangible® Hydra-PEG® Contact Lenses, when placed on the cornea, act as a refracting medium to focus light rays on the retina. The toric lens provides a more even surface over the uneven astigmatic cornea and thus helps to focus light rays on the retina.

Zenlens® and Zenlens® with Tangible® Hydra-PEG® Contact 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 YOUR ZENLENS® OR ZENLENS® WITH TANGIBLE® HYDRA-PEG® CONTACT LENSES WHILE SLEEPING.

INDICATIONS (USES)

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

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.

Zenlens® and Zenlens® with Tangible® Hydra-PEG® Contact Lenses in the scleral lens design 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).

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

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

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE Zenlens® or Zenlens® with Tangible® Hydra-PEG® Contact 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, except where prosthetic lens is required
- 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 Boston XO®, Boston XO_2® or OPTIMUM GP (roflufocon D and E) Contact Lens Materials
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated
- Patient is 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 directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Daily wear lenses are **not** indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when 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.
- 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 his or her eye care practitioner.

PRECAUTIONS

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

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

  Lens Type Center / Color Thickness
  Boston XO®, Boston XO_2®, Optimum GP - Blue > 0.65 mm
  Boston XO®, Boston XO_2®, Optimum GP - Ice Blue > 0.65 mm
  Boston XO®, Boston XO_2®, Optimum GP - Green > 0.55 mm
  Boston XO®, Boston XO_2®, Optimum GP - Violet > 0.65 mm

Special Precautions for Eye Care Practitioners:

- Zenlens® and Zenlens® with Tangible® Hydra-PEG® Contact Lenses are packaged non-sterile in a preserved aqueous solution, Boston SIMPLUS® Multi-Action Solution that contains poloxamine, hydroxyalkylphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, glucam and preserved with polyaminopropyl biguanide (0.0005%), chlorhexidine gluconate (0.003%). If a patient has experienced a prior history of allergy to any of the ingredients in the Boston SIMPLUS® Multi-Action Solution, do not dispense the lenses.
- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers.

  Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.
- Aphakic patients should not be fitted with Zenlens® or Zenlens® with Tangible® Hydra-PEG® Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eye care practitioner's office, the patient should be able to properly remove lenses or should have someone else available who can remove the lenses for him or her.
- Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- The presence of the ultraviolet (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 often cannot be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
  - Do not heat the conditioning/storage solution and/or lenses. Keep them away from extreme heat.
  - Always use **fresh, unexpired** lens care solutions.
  - Always follow directions in the package inserts for the use of contact lens solutions.
  - Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp Zenlens® Contact Lenses.
  - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
  - Sterile, unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
  - 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, they must first be cleaned, rinsed with sterile unpreserved solutions and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfected prior to insertion.
  - Zenlens® and Zenlens® with Tangible® Hydra-PEG® Contact Lenses must be stored in the lens storage case with the recommended solutions. Dry storage is not recommended.
- If the lens sticks (stops moving) on the eye, the patient should be instructed to follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eye care practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions 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 gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Patients should be advised about wearing lenses during sporting and water related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing and hot tubs may increase the risk of ocular infection including but not limited to *Acanthamoeba* keratitis.
- Instruct patient to inform his or her health care practitioner (doctor) that the patient wears contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Instruct the patient to contact his or her eye care practitioner before using any medicine in their eyes.
- Instruct the patient to inform his or her employer that he or she wears contact lenses. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to ensure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Certain atmospheric or environmental conditions can cause eye irritation. Consult your eye care practitioner regarding the use of contact lenses when these conditions exist.

Never wear lenses beyond the period recommended by the eye care practitioner.

Contact lenses should never be shared between users.

ADVERSE REACTIONS

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

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on the 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 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 storage 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 reinsert it. After reinsertion, if the problem continues, the patient should **immediately remove the lens 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 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 condition might become worse when a lens is used on an eye with an irregular cornea condition. The patient should be instructed to avoid serious eye damage by contacting the eye care practitioner IMMEDIATELY if there is an increase in symptoms while wearing the lens.

FITTING

Conventional methods of fitting scleral contact lenses apply to Zenlens® and Zenlens® with Tangible® Hydra-PEG® Contact Lenses. For a detailed description of the fitting techniques, contact:

Bausch & Lomb Incorporated
6 Lancaster Pkwy
Lancaster, NY 14086 USA
1-800-253-3669

WEARING SCHEDULE

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER. Patients tend to overwear 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.

Zenlens® and Zenlens® with Tangible® Hydra-PEG® Contact Lenses are indicated for daily wear. The suggested wearing time for these lenses 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

Regular checkups, as determined by the eye care practitioner, are also extremely important.

WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

LENS CARE DIRECTIONS

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

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

1. Rub and Rinse Time

Instruction for Use:

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

WARNING:

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

2. Soaking and Storing Your Lenses

Instruction for Use:

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

WARNING:

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

3. Lens Case Care

Instruction for Use:

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

WARNING:

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

4. Water Activity

Instruction for Use:

Do not expose your contact lenses to water while you are wearing them.

WARNING:

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

5. Discard Date on Solution Bottle

Instruction for Use:

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

WARNING:

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

BASIC INSTRUCTIONS

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

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

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

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

RECOMMENDED LENS CARE PRODUCTS

The eye care practitioner should recommend a care system that is appropriate for the Zenlens® and Zenlens® with Tangible® Hydra-PEG® Contact 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 Bausch + Lomb for use with Zenlens® and Zenlens® with Tangible® Hydra-PEG® Contact Lenses made with Boston XO®, Boston XO_2® or OPTIMUM GP (roflufocon D and E) Contact Lens Materials. Eye care practitioners may recommend alternate products that are appropriate for the patient's use with his or her contact lens(es).

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

Enzyme cleaning may be recommended by the eye care practitioner. 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. Enzymatic cleaner is NOT recommended for use with lenses coated with Tangible® Hydra-PEG®.

LENS CARE TABLE for Zenlens® lenses
(without Tangible® Hydra-PEG® treatment)

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

LENS CARE TABLE for Zenlens® lenses
(with Tangible® Hydra-PEG® treatment)

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

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

LENS CLEANING, DISINFECTION, AND STORAGE

Clean one lens first (always the same lens first to avoid mix-ups), **rinse** the lens thoroughly with recommended saline 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, disinfect lenses using the system recommended by the manufacturer 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.

After removing the lenses from the lens 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 storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

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

Eye care practitioners may recommend a weekly enzymatic cleaner which can be used to effectively remove protein deposits from Zenlens® Contact Lenses manufactured from Boston XO®, Boston XO_2® or OPTIMUM GP (roflufocon D and E) Contact Lens Materials. Enzymatic cleaner is NOT recommended for use with lenses coated with Tangible® Hydra-PEG®.

Zenlens® and Zenlens® with Tangible® Hydra-PEG® Contact Lenses **cannot** be heat (thermally) disinfected; warping may result.

LENS CARE REGIMEN

Patients must adhere to the lens care regimen recommended by their eye care practitioner for the lens care of Zenlens® and Zenlens® with Tangible® Hydra-PEG® Contact Lenses. Failure to follow this procedure can lead to severe infection, vision loss, or blindness.

CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (cannot be removed), the patient should be instructed to apply 1 to 3 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 15 minutes, the patient should IMMEDIATELY consult the eye care practitioner.

STORAGE

The Zenlens® and Zenlens® with Tangible® Hydra-PEG® Contact Lenses must be stored only in the recommended solutions.

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

Each lens is supplied (non-sterile) in a plastic lens storage case or plastic vial filled with Boston SIMPLUS® Multi-Action Solution. The lens package is labeled with the base curve, diopter power, diameter, center thickness, color, lot number, and expiration date. 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 Zenlens® and Zenlens® with Tangible® Hydra-PEG® Contact Lenses should be reported to:

Bausch & Lomb Incorporated
6 Lancaster Pkwy
Lancaster, NY 14086 USA
1-800-253-3669