



Package Insert Version Zenlens 2016.3
Gas Permeable Contact Lenses for Daily Wear

Alden Optical - Zenlens Catalog No. **AOZNS**
(Boston XO – hexafocon A, Boston XO2 – hexafocon B)

Alden Optical – Zenlens Toric Catalog No. **AOZNT**
(Boston XO – hexafocon A, Boston XO2 – hexafocon B)

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 patients prescribed lens.

INTRODUCTION
Zenlens Contact Lenses are manufactured from Boston XO® (hexafocon A), or Boston XO2® (hexafocon B) a gas permeable plastic material with and without an UV absorber. They are intended for *daily wear use only*. It is essential that you follow the recommended handling, cleaning and storage procedures. Failure to do so may eventually impair the performance of your lenses.

DESCRIPTION
Zenlens Contact Lenses manufactured using Boston XO® (hexafocon A) is a gas permeable contact lens material composed of siloxanyl fluoromethacrylate copolymer. The Boston XO material contains an ultraviolet absorber (MHB).

Zenlens Contact Lenses manufactured using Boston® XO2 (hexafocon B) is a gas permeable contact lens material composed of siloxanyl fluoromethacrylate copolymer. The Boston XO2 is available with or without an ultraviolet absorber (Uvulvin D-49 or MHB).

The Boston XO and Boston XO2 contact lens material is supplied by Bausch + Lomb, Inc.

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

- Sagittal Depth Range 3.200 to 6.700
- Chord Diameter: 16.0 mm and 17.0mm
- Spherical Powers (toric lenses): -20.00 D. to +20.00 D.
- Spherical Powers (spherical lenses) -20.00 D. to +20.00 D.
- Cylinder Powers, (toric lenses) -0.50 D. to -9.00 D.
- Advanced Peripheral System (APS) Steep-10 thru Steep-1, Standard, Flat-1 thru Flat-10 (in 30 micron increments)
- Options: Toric Peripheral Curves (APS)
Flexure Control Profile
Custom Center Thickness
Front Toric Rx

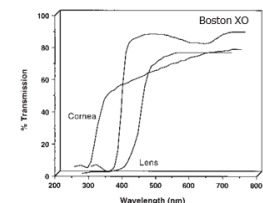
Physical/Optical Properties of Zenlens Contact Lenses manufactured with Boston XO Material:

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 (640 nm) 8.5 Blue
Light Absorbance (640 nm) 5.3 Ice Blue
Light Absorbance (585 nm) 5.3 Violet
Light Absorbance (640 nm) 4.9 Green
(Absorbance units/inch)

Light Transmittance* 92% *Average %T (400-800nm)
Surface Character Hydrophobic
Wetting Angle 49°
Water Content <1%
Oxygen Permeability 140* (100**)
[x 10-11 (cm3O2 • cm)/(cm2 •sec • mmHg) @ 35° C]



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

Physical/Optical Properties of Zenlens contact Lenses manufactured with Boston XO2 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. Solvent Yellow No. 18

Specific Gravity 1.19
Refractive Index 1.424

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

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

Surface Character	Hydrophobic
Wetting Angle	38°
Water Content	<1%
Oxygen Permeability:	
Edge Corrected	141**
Non Edge Corrected	161**

*gas to gas method
**polarographic method (ISO/Fatt)

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.

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.

WEARING RESTRICTIONS AND INDICATIONS

Zenlens 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 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 CONTACT LENSES WHILE SLEEPING.

INDICATIONS (Uses)

Zenlens Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) 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 LASIK surgery. The lens may be disinfected using a chemical disinfection (not heat) system only.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE ZENLENS 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 or Boston XO2 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 Contact Lenses are not sterile when shipped from Alden Optical. Prior to dispensing, clean and disinfect the lens (es) according to the appropriate lens care regimen.

• 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 and Boston XO2 - Blue > 0.65 mm
Boston XO and Boston XO2 - Ice Blue > 0.65 mm
Boston XO and Boston XO2 - Green > 0.55 mm
Boston XO and Boston XO2 - Violet > 0.65 mm

Special Precautions for Eye Care Practitioners:

• 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 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 water 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.

• 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.

• Instruct patient to ask his or her Eye Care Practitioner about wearing lenses during water activities and other sports.

• 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 assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

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; 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.**

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.

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 problems 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.

FITTING

Conventional methods of fitting contact lenses apply to ZENLENS CONTACT LENSES. For a detailed description of the fitting techniques, refer to the ALDEN SOFT CONTACT LENSES Professional Fitting and Information Guide, copies of which are available from:

Alden Optical
 3 Lancaster Pkwy
 Lancaster, NY 14086 USA
 (716) 937-9181

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.

Zenlens 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
 - 3 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.

WARNING: Zenlens (gas permeable) Contact Lenses are **NOT** intended for overnight (extended) wear. WEARING THE LENSES WHILE SLEEPING INCREASES THE RISK OF INFECTION AND PERMANENT DAMAGE TO VISION.

WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

Certain atmospheric or environmental conditions can cause eye irritation, consult your eye care practitioner regarding the use of contact lenses when these conditions exist.

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)

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.

The lens care products listed below are recommended by Bausch & Lomb for use with Zenlens Contact Lenses made with Boston® XO and XO2 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 CARE TABLE

Product	Lens Care System Purpose	Chemical (Not Heat)
Clean	Boston ADVANCE® Cleaner or Boston® Cleaner	
Disinfect	Boston ADVANCE® Comfort Formula Conditioning Solution or Boston® Conditioning Solution	
Store	Boston ADVANCE Comfort Formula Conditioning Solution or Boston Conditioning Solution	
Multi-Action (Clean, Condition, Disinfect, Rinse and Cushion)	Boston SIMPLUS® Multi-Action Solution	
Lubricate/ Rewet	Boston® Rewetting Drops	
Weekly Enzymatic	Boston® ONE STEP Liquid Enzymatic Cleaner	

Cleaner

- **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 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.

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 or Boston XO2 lens materials.

Zenlens Contact Lenses **cannot** be heat (thermally) disinfected, warping may result.

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 cleaner to each surface. Then rub the lens between your fingers for 20 seconds.
3. AFTER CLEANING, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution for approximately 10 seconds.
4. Fill contact lens carrying case with the recommended disinfection and storage solution and place lenses in the proper cells and soak as recommended in solution labeling.

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 saline solution prior to placement on the eye should reduce the potential for irritation.

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 storage solution. Replace lens case at regular intervals as recommended by the lens case manufacture or your eye care practitioner.

Lens Care Regimen:

Patients must adhere to the lens care regimen recommended by their eye care practitioner for the lens care of ZENLENS (gas permeable) CONTACT LENSES. Failure to follow this procedure may result in development of serious ocular infections

Care for a sticking (nonmoving) lens:

If the lens sticks (cannot be removed), the patient should be instructed to apply 3 to 4 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 (gas permeable) CONTACT LENSES must be stored only in the recommended solutions. If left exposed to the air, the lenses will dehydrate. If lens dehydrates, reference above section on conditioning solution.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

Enzyme cleaning may be recommended by the eyecare 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.

RECOMMENDED LENS CARE PRODUCTS

The eyecare practitioner should recommend a care system that is appropriate for the ZENLENS (gas permeable) CONTACT LENS. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

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 (nonsterile) in a plastic lens storage case. The case is labeled with the base curve, diopter power, diameter, center thickness, color, UV-absorber (if present) and lot number. Additional parameters maybe 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 (gas permeable) CONTACT LENSES should be reported to:

Alden Optical
 6 Lancaster Pkwy
 Lancaster, NY, 14086 USA
 (716) 937-9181

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