Package Insert Version Zenlens™ 2016.1

Alden Optical – Zenlens®

Physical/Optical Properties of Zenlens™ Contact Lenses manufactured with Boston XO™ Material:
The listed lenses contain the following color additivess:

<table>
<thead>
<tr>
<th>Color</th>
<th>Color Additive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue</td>
<td>D &amp; C Green No. 6</td>
</tr>
<tr>
<td>Ice Blue</td>
<td>D &amp; C Green No. 6</td>
</tr>
<tr>
<td>Violet</td>
<td>D &amp; C Green No. 6</td>
</tr>
<tr>
<td>Green</td>
<td>D &amp; C Green No. 6</td>
</tr>
<tr>
<td>Yellow</td>
<td>D &amp; C Green No. 18</td>
</tr>
<tr>
<td>Pink</td>
<td>C.I. Solvent Yellow No. 18</td>
</tr>
</tbody>
</table>

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-blocking eyewear such as UV-blocking goggles or sunglasses. Persons who continue to use these lenses may be exposed to harmful UV radiation.

DESCRIPTION OF LENSES
Zenlens™ Contact Lens manufactured using the OPTIGUM® (refrufoxin D, and E) for Daily Wear is a rigid gas permeable methacrylate copolymer of Methyl methacrylate, 1,1,1,3,3,3-Hexafluoropropyl Methacrylate, Methacryloyloxypropyl Trimethoxysilane, 1.3-bis(methacryloyloxy)-1,3,3,3-tetraakis (trimethylsiloxy) disiloxane, 2-Hydroxymethyl Methacrylate, and Methacryloyloxypropyl dimethoxymethylsilane.
The OPTIGUM® (refrufoxin D, and E) Contact Lens for Daily Wear incorporates an ultraviolet absorber (MHB). The tinted lenses contain more than one of the following color additivess:

<table>
<thead>
<tr>
<th>Lens Material</th>
<th>Color Additive</th>
</tr>
</thead>
<tbody>
<tr>
<td>D &amp; C Green</td>
<td>No. 6, FD &amp; C Red No. 17, CI Solvent</td>
</tr>
<tr>
<td>Yellow</td>
<td>Yellow 18</td>
</tr>
<tr>
<td>Blue</td>
<td>Blue</td>
</tr>
<tr>
<td>Ice Blue</td>
<td>Ice Blue</td>
</tr>
<tr>
<td>Violet</td>
<td>C.I. Solvent Yellow No. 18</td>
</tr>
</tbody>
</table>

The physical properties of the OPTIGUM® are:

<table>
<thead>
<tr>
<th>Property</th>
<th>Refractive Index</th>
<th>Light Transmission†</th>
<th>Water Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>D &amp; C Green</td>
<td></td>
<td></td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>

MENTIONS
Contact Lenses when placed on the cornea act as a refracting medium to focus light rays on the retina. The 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, astigmatism and presbyopia) in aphatic and non-aphatic 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. LASKR) surgery.

Scleral lenses manufactured with the Boston XO™ and Boston XO® 2, gas permeable materials 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 (bacterial, fungal, or viral), trauma, keratoconus, as a result of an oxygen starvation syndrome, refractive surgery (e.g. LASKR or radial keratotomy) or corneal transplantation. Causes may also include corneal degeneration (e.g. keratoconus, keratoebulbus, marginal degeneration, Salzmann’s nodular degeneration, and corneal dysphoria (e.g., lunate dysopia, granular corneal dysphoria, Reis-Bucklers dysopia, Cowdry’s dysopia).

Scleral lens designs for daily wear manufactured with the Boston XO™ and Boston XO® 2 have avascular corneal diameters and are also indicated for therapeutic use in eyes with corneal surface disease (e.g. corneal Gruetz-host disease, Gypfs’s syndrome, dry eye syndrome and Fuch’s dystrophy). Implant failure and corneal inflammation (e.g. herpes simplex, herpes zoster, Familial Dystropho), 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 corneal surface, 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™ CONTACT LENSES when any of the following conditions are present:

- Acute and subacute infection or inflammation of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids, except where prosthesis lens is required
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoxia (reduced corneal sensitivity), if not aphatic
- Any systemic disease that may affect the eye be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exacerbated 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 clean for Boston XO™ or Boston XO® Contact Lens Materials

WARNING
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 lens surface is less free of serious adverse reactions when patients wear daily lenses overnight.

• Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than non-smokers.

• If contact lenses become foggy, hazy, or scarred, redness or pain 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 insertion, cleaning, and disinfecting the lenses(s) 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®, Boston XO®, Opti Kam - GP - Blue 0.65 mm
  Boston XO®, Boston XO®, Opti Kam - Ice Blue 0.65 mm
  Boston XO®, Boston XO®, Opti Kam - Green 0.55 mm
  Boston XO®, Boston XO®, Opti Kam - 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 power, 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 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.

• Aesthetic patients should not be fitted with Zenlens™ Contact Lenses until the determination is made that the condition is completely resolved.

• 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 material 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 contact lenses. Use only recommended solutions.

• Do not heat the conditioning/storage solution and/or lenses. Keep them away from direct heat. If heating is necessary, place the lenses in a clean, dry lens storage case. Ideally, these lenses should be heated 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.

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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 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.

Lens Care Regimen:
Patients must adhere to the lens care regimen recommended by their eye care practitioner for the lens care of Zenlens™ 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 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™ 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 (nonsterile) 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™ Contact Lenses should be reported to:
Alden Optical
6 Lancaster Pkwy
Lancaster, NY, 14086 USA
1-800-253-3669

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