FRONT PANEL VISIBLE UPON FOLDING

DESCRIPTION - BOSTON XO

INDICATIONS (USES):

- Temporarily reduces up to 5.00 diopters of myopia.
- For orthokeratology fitting program for myopic correction.
- For daily wear in an orthokeratology fitting program for myopic correction.
- Generally retains its altered shape for part or all of the wearing time.
- Severe insufficiency of tears (dry eyes).
- Clinical studies have demonstrated that contact lens wearers who are smokers have a higher incidence of eye complications.
- Studies have shown that contact lens wearers should see their eye care practitioner if eyes become red or irritated.
- Sterile unpreserved solutions, when used, can affect the cornea, conjunctiva or eyelids.
- Any active corneal infection (bacterial, fungal, sensitivity).
- Corneal hypoesthesia (reduced corneal sensation).
- Blurred vision, rainbows, or halos around lights.
- Redness of the eyes.
- Inform your doctor (health care practitioner) if these or any other problems persist or worsen.

WARNINGS:

- If eyes become red or irritated, discontinue use and consult your eye care practitioner.
- If tolerance or effectiveness is not achieved within the first 30 days, it is likely that the lenses will not work.
- If lenses become stuck, remove them carefully and see your eye care practitioner.
- Glasses are recommended for activities where contact lenses might be dislodged or lost.
- Glasses are recommended for driving.
- Wear glasses for outdoor activities when not wearing contact lenses.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO):

- If blurred vision, rainbows, or halos persist, discontinue use and consult your eye care practitioner.
- If redness of the eyes occurs, discontinue use and consult your eye care practitioner.
- If tolerance or effectiveness is not achieved within the first 30 days, it is likely that the lenses will not work.
- If lenses become stuck, remove them carefully and see your eye care practitioner.

CLINICAL STUDY RESULTS:

- 20/20 for 99 eyes, 20/40 for 109 eyes and one eye.
- 20/20 or better for 104 eyes and 20/40 or better of the patient and lens performance on the day of the study.

- 20/20 or better in relation to the initial myopia reduction is shown in the following table:

<table>
<thead>
<tr>
<th>Myopia</th>
<th>REDUCTION</th>
<th>BETTER</th>
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<tbody>
<tr>
<td>-2.00</td>
<td>2.40</td>
<td></td>
</tr>
<tr>
<td>-1.00</td>
<td>0.80</td>
<td></td>
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<tr>
<td>0.00</td>
<td>0.00</td>
<td></td>
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<tr>
<td>1.00</td>
<td>1.60</td>
<td></td>
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<tr>
<td>2.00</td>
<td>2.40</td>
<td></td>
</tr>
</tbody>
</table>

HOW SUPPLIED:

- Cases can be a source of bacteria.
- Contact lens cases should be replaced at regular intervals as recommended by the manufacturer or eye care practitioner.
- Lens cases should be cleaned in the palm of the hand rather than between the fingers.
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Care practitioner should provide but should be made available to
Flatter or steeper than Secondary Curves 0.10 to 2.00 mm
Low Minus Lens: 0.10 to 0.30 mm
#6 Green and C.I. Solvent Yellow #18 for green polymer, hexafocon A, with water content of
It is essential to follow your eye care practitioner of the anterior segment of the eye.
Any eye disease, injury, or abnormality that
BOSTON XO contact lenses for orthokeratology wearers should see their eye care practitioner
sive tearing, vision changes, or redness of the ulcers, can develop rapidly and lead to loss of
WARNINGS:
• Always wash and rinse hands before handling
• Always keep the lenses completely immersed
• Do not use saliva or anything other than the

ADVERSE EFFECTS (PROBLEMS AND WHAT TO
• Reduced sharpness of vision (poor visual
• Unusual eye secretions.

For the 110 eyes that completed this study, ed to achieve full or partial temporary refractive reduction is shown in the following table:

<table>
<thead>
<tr>
<th>Time Worn</th>
<th>Percent of patients</th>
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<tbody>
<tr>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>4</td>
<td>8</td>
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<td>5</td>
<td>9</td>
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<tr>
<td>6</td>
<td>10</td>
</tr>
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</table>

There was considerable variability, however, as there is a tendency for some patients to remind patients to adhere to the maximum sleep. There is a tendency for some patients to avoid serious eye damage.

Three months  8.4 hours/day

Three month clinical, 8% showed no change in

1400 North Goodman Street

Print Date: 09/07                     3629902

Bausch & Lomb Incorporated.
Federal (U.S.A.) law restricts this device for the eye care practitioner to provide.

The physical properties of BOSTON XO are:

- Oblate, Prolate or Tangent Conic
- Flatter or steeper than

LENS PARAMETERS AVAILABLE:

- #17 for red lenses and C.I. Solvent Yellow #18
- #6 Green and C.I. Solvent Yellow #18

The percentage of eyes that achieved uncorrected vision of 20/20 or better for 104 eyes and 20/40 or better with up to 3.00 diopters of myopia. For patients requiring BOSTON XO contact lenses for orthokeratology:

- Studies have shown that contact lens wearers are to be worn on a daily wear basis only. Do not use BOSTON XO Contact Lenses when on a prescribed wearing schedule.

- Patients should be advised NOT TO SLEEP while wearing lenses, exercise caution and take care with the lenses. Contact lens cases can be a source of bacteria and should be discarded after the time specified on the label. Some solutions may have more than 1% percent. The tinted lens contains less than 1% percent. The lens should move freely on the cornea, but BOSTON XO contact lenses for orthokeratology and can influence the corneal shape. The amount of corneal flattening is properly reduced. The lens may reduce the focusing power of the eye, and if a temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes.

- The continuing ocular health needs; therefore, the continuing ocular health should be carefully monitored. The case, packing slip or invoice should be instructed to keep the lens off the eye should be carefully monitored.

DO NOT USE BOSTON XO Contact Lenses when on a prescribed wearing schedule.

CONTRAINDICATIONS (REASONS NOT TO USE):

- Specific Precautions
- Allergic reactions of ocular surfaces or adnexa
- Contact lens cases can be a source of bacterial contamination of the anterior segment of the eye.
- Contact lens cases can be a source of harmful germs. To minimize lens warpage, there is a tendency for some patients to be exacerbated by wearing RGP contact products. Eye problems, including corneal sensitivity.
- Chronic eye conditions such as infection, corneal ulcer, foreign objects on it, or the problem stops
- As with any contact lens, follow-up visits are necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy any of the following conditions exist:
- • Patients should be informed that the following schedule depends upon the previous contact lens experience.
- • Allergic reactions of ocular surfaces or adnexa
- • Clinical studies have demonstrated that contact lens wear must be continued to maintain the corneal shape. Studies have shown that contact lens wearers
- • Always handle your lenses carefully and avoid putting them in your eye.
- • Sterile unpreserved solutions, when used, should be discarded after the time specified on the label. Use only a chemical lens care system.
- • Use recommended solutions with the contact lenses. Recommended solutions for lubricating or wearing the lenses.
- • Contact lens cases can be a source of bacterial contamination of the anterior segment of the eye.
- • If aerosol products such as sprays are used together, and not all types of solutions are recommended solutions.
- • Use only a chemical lens care system. Use of recommended solutions may have more than 1% percent. The tinted lens contains less than 1% percent.
- • Blurred vision, rainbows, or halos around any of the following conditions exist:
- • Reduced sharpness of vision (poor visual acuity).
- • Unusual eye secretions.
- • Ears tingling, burning, itching (irritation), or be exacerbated by wearing RGP contact products. Eye problems, including corneal sensitivity.
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- WEARING TIME
- Time Worn
- Percent of patients

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BOSTON XO
Rigid Gas Permeable (RGP) contact lenses for orthokeratology

**Physical Properties**
- Peripheral Curves: 0.10 to 2.0 mm
- Secondary Curves: 0.10 to 2.00 mm

**Usage Recommendations**
- Wear only and should not be worn overnight.
- Use with appropriate lens design and parameter.

**Tint Transmittance**
- 52% Light Transmission*

**Oxygen Permeability**
- 140** (100***)

**Contact Receding Angle**
- polarographic method (ISO/Fatt)

**Precautions**
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva or eyelids.
- Acute and subacute inflammations or infections.
- Conditions that cause severe tearing, vision changes, or redness of the eye.
- Conditions that affect the corneal curvature, refractive indices of the solutions
- Any eye condition that might be exacerbated by wearing RGP contact lenses.

**Contraindications**
- Myopia reduction, lens wear must be continued after treatment. There was an insignificant difference in the percentage of patients that achieved 20/20 or better.

**Schedule**
- **Daily Wear**
  - One month: 8.0 hours/day
  - Two months: 12.0 hours/day
  - Three months: 16.0 hours/day

**Contact Care**
- Use of BOSTON XO Contact Lens Care System.

**Contact Lens Case**
- Rinse thoroughly with a sterile solution and replace the lens case monthly.

**Handling Precautions**
- Always use fresh unexpired lens care solutions together, and not all types of solutions are safe for use with all lenses. Use only recommended solutions.
- Carefully follow the handling, insertion, and removal instructions.

**Solution Precautions**
- Always use fresh unexpired lens care solutions.
- Do not heat the wetting/soaking solutions.
- Always contact your eye care practitioner before adding medications to lens solutions.

**Lens Case Precautions**
- Never use tweezers or other tools to remove the lens from the case.
- To minimize lens warpage during cleaning, soak the lens in the case for 24 hours before cleaning.

**Visibility of the lens**
- The percentage of patients that can be expected to achieve 20/20 or better in relation to the initial myopia is given in the above table. A total of 43 (39%) patients achieved a visual acuity of 20/20 or better.

**Sticking Lens**
- In the patient information booklet. The lens should move freely on the eye.
The physical properties of BOSTON XO are:

- Oblate, Prolate or Tangent Conic
- Powers: -10.00 to +3.00 Diopters
- Base Curve: Secondary Curves 0.10 to 2.00 mm
- Center Thickness for Chord Diameter: Approx 6.5 to 11.5

Regular RGP contact lenses are designed to correct irregular astigmatism, keratoconus, and severe keratoconus in patients who have not previously worn contact lenses.

Contact lenses rest directly on the corneal tear film, and BOSTON XO contact lenses for orthokeratology provide a regular RGP design.

The amount of myopia reduced varied between patients and could not be predicted prior to the study and those with no previous contact lens experience.

A total of 138 eyes were enrolled in the clinical study. The amount of myopia reduced varied between patients and could not be predicted prior to the study.

BOSTON XO is a trademark of Bausch & Lomb Incorporated

1400 North Goodman Street
Rochester, New York 14609

1400 N. Goodman Street
9161 East Independence Blvd
Indianapolis, Indiana 46256

Contact lenses manufactured from the BOSTON 1400 family of products can result in serious injury to the eye.

Incorrect use of contact lenses and lens care products can result in serious injury to the eye. A lens care booklet is included with each lens case. The lens should move freely on the hand rather than between the thumb and fingers. Check the hands for any foreign material before touching your lenses.

Do not touch the lens with your fingernails.

Always handle your lenses carefully and avoid contact with foreign material. 

• Always wash and rinse hands before handling lenses.

• Always wash and rinse hands thoroughly before handling contact lenses.

• Never wear your contact lenses beyond the expiration date.

• Do not wear your lenses while sleeping, at the risk of severe eye injury.

• If you notice any of the above: IMMEDIATELY REMOVE YOUR LENSES. If the discomfort or foreign body sensation persists, see your eye care practitioner.

• Excessive watering (tearing) of the eyes.

• Unusual sensitivity or irritation of the eye.

• Vision problems.

• Ask your eye care practitioner about wearing contact lenses in water activities.

• Green 90%

• Tint Transmittance

• Light Transmission*

• Water Content <1 %

• Specific Gravity 1.27

• Wetting Angle 49°
BOSTON XO®
PERMEABLE CONTACT

CAUTION:

FOR Low Minus Lens: 0.10 to 0.30 mm Chord Diameter Approx 6.5 to 11.5
polymer, hexafocon A, with water content of

 Diopters in non-diseased eyes. The lens may

flattening or the myopia will revert back to the

correct focus and compensate for myopia. After

flattened, this reduces the focusing power of

Contact lenses rest directly on the corneal tear

controlled, it is possible to bring the eye into

the amount of corneal flattening is properly

reduces the focusing power of the eye, and if

produce a temporary reduction of myopia by

Water Content <1 %  

Ice Blue 90%

Tint Transmittance

 Franco, New York 14609

• Any eye disease, injury, or abnormality that

adverse reactions than nonsmokers.

infections or ulcers.

BOSTON XO contact lenses for orthokeratology

by your eye care practitioner. All contact lens

materials are effective for their intended use.

• Allergic reactions of ocular surfaces or adnexa

wearing RGP contact lenses or use of contact

sterile unpreserved solutions, when used,

• Do not heat the wetting/soaking solution

removal, cleaning, disinfecting, storing and

in the recommended storage solution when

in the labeling directions. A heat (thermal) lens care system can cause

and lenses.

• Avoid, if possible, all harmful or irritating

practitioner.

• To minimize lens warpage during cleaning,

practitioner. If the lens has dirt, an eyelash, or other

• Blurred vision, rainbows, or halos around

require that you not wear contact lenses.

the use of eye protection equipment or may

recommended follow-up schedule.

before using any medicine in your eyes.

• Lens cases should be replaced at regular

age to their eyes or lenses.

included all design configurations or lens

parameters that are presently available in the

booklet. The lens should move freely on the

parameters that are presently available in the

should IMMEDIATELY remove the contact lens-

• Be certain that your fingers or hands are free

manufacturer. Telephone

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