DESCRIPTION: Boston VST PIB Ins / US / WILM
PART No.: 8146902
SPEC No. or SPEC DIMENSIONS: 500556
SPECIAL INSTRUCTIONS: LENS0202.WF

PAINT SUPPLIERS: Please refer to Valeant’s Paint Supplier Guidelines
INSTRUCTION
The Boston Orthokeratology (oprifocon A) Shaping Lens is a professional device used to help improve a patient’s vision. The lens is made of a material that temporarily softens and greatly reduced oxygen permeability, but has been tested at a high laboratory temperature and has been shown to meet or exceed the requirements for clinical use. The Boston Orthokeratology (oprifocon A) Shaping Lens is placed on a patient’s eye and then left in place overnight. However, the lens may be removed during sleep if the patient desires.

HOW THE BOSTON ORTHOKERATOLOGY (OPRIFOCON A) SHAPING LENS FUNCTIONS

The Boston Orthokeratology (oprifocon A) Shaping Lens is designed to temporarily reshape the cornea to improve vision. The lens is made of a material that temporarily softens and greatly reduced oxygen permeability, but has been tested at a high laboratory temperature and has been shown to meet or exceed the requirements for clinical use. The Boston Orthokeratology (oprifocon A) Shaping Lens is placed on a patient’s eye and then left in place overnight. However, the lens may be removed during sleep if the patient desires.

ALTERNATIVE WAYS TO CORRECT HYPERMETROPIC AND HYPERopic Vision

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PRECAUTIONS

General The following precautions are for the Boston Orthokeratology (oprifocon A) Shaping Lenses. Other side effects, which may occur, include discomfort or foreign body sensations, redness, tearing, photophobia, and some degree of edema and corneal staining. It is anticipated that these symptoms will be minimal and will not interfere with the patient’s ability to wear the lens.

Contraindications

• Any eye disease, injury, or abnormality that may be adversely affected by contact lenses.

• Any systemic disease which may affect the eye.

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**CLINICAL STUDY DATA**

**Adverse Events**

Adverse events reported in at least 5% of the subjects by at least one grade of severity:

<table>
<thead>
<tr>
<th>Event</th>
<th>Grade</th>
<th>Number of Subjects</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slight injection</td>
<td></td>
<td>55</td>
<td>11%</td>
</tr>
<tr>
<td>Moderate injection</td>
<td></td>
<td>11</td>
<td>2%</td>
</tr>
<tr>
<td>Severe injection</td>
<td></td>
<td>9</td>
<td>1%</td>
</tr>
</tbody>
</table>

**Post-lens removal**

The majority of the adverse events listed in the table above were not graded in severity. The adverse events were not considered to be related to the device, except for one case of cornea abrasion. This case was considered to be the result of an accidental injury, and the subject was advised to seek medical attention.

**DISCLAIMER**

The information provided in this document is for informational purposes only and is not intended to replace professional medical advice. The content is subject to change without notice, and it is the responsibility of the user to ensure that the information is up-to-date and accurate. The user is advised to consult a healthcare professional for any medical advice or treatment recommendations.

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**GLOSSARY**

Abnormal vision: A condition where vision is not normal.

Astigmatism: A condition where the cornea is not perfectly round.

Bifocal lenses: Lenses that have two focal points for different distances.

Contact lenses: Lenses that are worn on the eyes.

Corrected vision: Vision that is corrected with glasses or contact lenses.

Diabetic retinopathy: A complication of diabetes that affects the retina.

Epiretinal membrane: A condition where there is an excess of tissue on the retina.

Glaucoma: A condition where there is increased pressure in the eye.

Hypertensive retinopathy: A condition where there is high blood pressure in the eye.

Keratoconus: A condition where the cornea is not round.

Maculopathy: A condition where there is damage to the macula.

Myopia: A condition where vision is blurred at a distance.

Myopic control: A method to control myopia.

Nearsightedness: A condition where vision is blurred at a distance.

Ophthalmologist: A doctor who specializes in eye care.

Orthokeratology: A method to correct vision by reshaping the cornea.

Post-lens removal: The process of removing contact lenses from the eyes.

Presbyopia: A condition where there is difficulty seeing at a distance.

Ptosis: A condition where the lid droops.

Refractive error: An error in the refraction of light.

Retinopathy: A condition where there is damage to the retina.

Stabilization: The process of making the cornea more stable.

Surgical correction: A method to correct vision by surgical means.

Toric lenses: Lenses that have different powers in different meridians.

Vision correction: The act of correcting vision.

Wearing schedule: The schedule for wearing contact lenses.

**REFERENCES**

