Assembly Instructions

1. Bottle opening technique

2. Do not use if bottle is broken or damaged.

3. Screw the plastic rod into the plunger.

4. Unclamp the plunger and pull out the plastic rod.

5. Do not re-use this packaging.

Symbols Used On Sterile Packaging

- STERILE
- EU

Note: Refer to the separate Healon®5 and Healon®Duet® OVD texts in this package insert.

Applications

- Refractive surgery
- Cataract surgery
- IOL implantation
- Vitreoretinal surgery
- Retinal detachment
- Intraocular tumor removal
- Pneumatic retinopexy
- Postoperative management
- Intravitreal drug delivery
- Postoperative treatment
- Ocular trauma
- Ocular inflammation
- Ocular infection
- Ocular neovascularization
- Ocular dryness
- Ocular surface disease
- Ocular adhesion
- Ocular synechiae
- Ocular anterior chamber maintenence
- Ocular anterior segment maintenence
- Ocular uveitis
- Ocular uveitis resolution
- Ocular uveitis inflammation
- Ocular uveitis flare
- Ocular uveitis cell count
- Ocular uveitis intraocular pressure
- Ocular uveitis visual acuity
- Ocular uveitis surgical intervention
- Ocular uveitis complication
- Ocular uveitis complication resolution
- Ocular uveitis complication surgical intervention
- Ocular uveitis complication prevention
- Ocular uveitis complication prevention resolution
- Ocular uveitis complication prevention surgical intervention
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Healon EndoCoat®
Optimizes Neurosurgical Device
Product Description

Healon EndoCoat® is a neutral, highly viscoelastic solution designed to enhance surgical visualization and facilitate surgical procedures. It is ideal for use as an aid in anterior segment procedures, including cataract surgery and intraocular lens (IOL) implantation. Healon EndoCoat® is composed of sodium hyaluronate and is a sterile solution of sodium hyaluronate. The compound is ocular-grade sodium hyaluronate (Healon®) in human anterior segment.

Directions For Use

• For use as a surgical aid in anterior segment surgery, including:
  • Cataract surgery and intraocular lens (IOL) implantation: Inject Healon EndoCoat® into the anterior chamber to achieve optimal clarity during surgery. This solution can be used to position the vitreous face and prevent formation of a flat chamber during surgery. It may also be used to create a viscoelastic interface between tissues. Sodium hyaluronate does not interfere with the normal wound healing process. Sodium hyaluronate can also act as a viscoelastic space filler, maintaining a separation distance between tissues.

• To reduce the risk of early postoperative IOP spikes, Healon EndoCoat® is recommended prior to entering the eye, and excessive force on the plunger should be avoided.

• Do not use excessive amounts of Healon EndoCoat® as this may cause the hub to weaken and possibly detach from the syringe. Extrusion of a test droplet from the hub should be avoided.

Release

• Healon EndoCoat® is sterilized by gamma irradiation.

Bottle Contents

• The bottle contains Healon EndoCoat® in a 2.4 mL glass vial. Contents are sterile and are not to be mixed with other medications.

Additional Information

• Healon EndoCoat® is derived from microbial fermentation by a purified proprietary process.

Precautions

• Use only if solution is clear.

Contraindications

• This product is not intended for use in the eye.

Warnings

• All of the adverse reactions described above are potential adverse reactions for Healon EndoCoat®. It is recommended to monitor intraocular pressure (IOP) and handle the solution with care to minimize the risk of adverse reactions. Healon EndoCoat® is contraindicated in cases of IOP spikes ≥30 mm Hg and mean percent change in corneal endothelial cell count (ECC) between the preoperative and postoperative periods.

Adverse Events

• The observed mean percent changes in ECC from preoperative to three months postoperative for the percentage of subjects with an IOP spike ≥30 mm Hg and mean percent change in corneal endothelial cell count (ECC) between the preoperative and postoperative periods are provided in Table 8. Study results demonstrate that for the percentage of subjects with an IOP spike ≥30 mm Hg and mean percent change in corneal endothelial cell count (ECC) between the preoperative and postoperative periods, Healon EndoCoat® was statistically non-inferior to the control group and non-inferior to the fermented group.

Table 8: Change in ECC from Baseline to 3 Months (Safety Population- Paired Eye Subjects)

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Percent Change Minus Control OVD</th>
<th>a Percent Change=(Postop ECC Minus Preop ECC)/Preop ECC) with Difference= Fermented OVD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fermented OVD</td>
<td>206</td>
<td>2410.82 ± 420.16</td>
</tr>
<tr>
<td>Control OVD</td>
<td>206</td>
<td>2543.75 ± 355.64</td>
</tr>
</tbody>
</table>

Note: The table above demonstrates the statistical non-inferiority of Healon EndoCoat® in comparison to the control group. The percent change difference between groups of 1.11% (SD 11.89) is statistically non-inferior for the fermented group.

Visit

<table>
<thead>
<tr>
<th>Viscoelastic</th>
<th>Rate of IOP spikes (%)/Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healon EndoCoat® OVD</td>
<td>1 Week 199 2.5 (5)</td>
</tr>
<tr>
<td>Healon EndoCoat® OVD</td>
<td>1 Day 199 2.5 (5)</td>
</tr>
<tr>
<td>Healon EndoCoat® OVD</td>
<td>1 Week 199 1.0 (2)</td>
</tr>
<tr>
<td>Healon EndoCoat® OVD</td>
<td>1 Day 199 1.0 (2)</td>
</tr>
</tbody>
</table>

Note: The table above demonstrates the statistical non-inferiority of Healon EndoCoat® in comparison to the control group. The rate of IOP spikes is calculated as the percentage of patients with an IOP spike ≥30 mm Hg over the study period.

References

7. Healon EndoCoat® is a Trademark of Johnson & Johnson Surgical Vision, Inc.

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