and/or topical steroid treatments were administered) (5) and transient postoperative increases in
Healon® EndoCoat OVD can also be applied to the IOL before placement. During the procedure, more injection is made before phacoemulsification removal of the cataract and before insertion of the IOL.

INDICATIONS

Healon® EndoCoat OVD is an ophthalmic viscoelastic containing 3% sodium hyaluronate intended for use as a surgical aid in patients undergoing anterior segment procedures including:

- Cataract surgery with an intracapsular lens.
- Cataract surgery without an intracapsular lens.
- Secondary intraocular lens implantation.

Healon® EndoCoat OVD maintains the lens number during anterior segment surgery, aids in tissue manipulation during surgery, enhances visualization during the surgical procedure and protects the corneal endothelium from damage. The viscoelastic properties promote the normal position of the vitreous face and prevents formation of a flat chamber during surgery. It may also be used to cast internal lenses and instruments prior to tissueless intracapsular lens implantation.

CONTRAINDICATIONS

At present, there are no contraindications to the use of Healon® EndoCoat OVD when used as recommended.

WARNINGS

The Healon® EndoCoat OVD Delivery system is not designed or intended to be attached to instruments other than the one provided with the product. Failure to follow the “Directions for Use” may result in cannula detachment.

Mixing of quaternary ammonium salts, such as benzalkonium chloride, with sodium hyaluronate can result in the formation of a precipitate. The eye should not be irrigated with any solution containing benzalkonium chloride if Healon® EndoCoat OVD is to be used.

DIRECTIONS FOR USE

Cataract surgery and intraocular lens (IOL) implantation: Inject Healon® EndoCoat OVD slowly through the cannula into the anterior chamber. The use of Healon® EndoCoat OVD is most effective when the cannula is fastened securely to the syringe; however, over tightening may cause the cannula to detach. Use the cannula that is appropriate for the size of the cannula used by the surgeon. The eye should not be irrigated with any solution containing benzalkonium chloride if Healon® EndoCoat OVD is to be used.

Injection of viscoelastics creates pressure in the syringe. To prevent expulsion of the cannula from the eye, ensure that the cannula is securely attached to the fitting on the syringe. Injection of viscoelastics into the anterior segment or into the posterior chamber may cause injury to the lens capsule and iris. If the eye becomes compressed, remember that the anterior chamber may collapse.

Adverse Reactions

Because sodium hyaluronate is a polysaccharide, it can cause anaphylaxis in patients who have a history of allergy to this product. Healon® EndoCoat OVD should not be used to remove vitreous humor.

Sodium hyaluronate is a linear polymer consisting of repeating disaccharides of sodium glucuronate and N-acetylgalactosamine found throughout the body with high concentrations in the vitreous humor, synovial fluid, and articular cartilage. It is used in the eye in a variety of organic solvents.

CHARACTERISTICS

Sodium hyaluronate is a linear polysaccharide polymer consisting of repeating disaccharides of sodium glucuronate and N-acetylgalactosamine found throughout the body with high concentrations in the vitreous humor, synovial fluid, and articular cartilage. It is used in the eye in a variety of organic solvents.

Sodium hyaluronate has a high molecular weight and does not interfere with the normal way the healing process. Sodium hyaluronate also is present in the capsule material of certain bacteria. These bacteria may be cultured by a fermentation process to yield sodium hyaluronate. Sodium hyaluronate extracted and purified from different sources can have different molecular weights but has the same molecular structure. The sodium hyaluronate in Healon® EndoCoat OVD is a highly purified extract of a bacterial fermentation and is tolerated well in the eye. It has an average molecular weight of approximately 600,000 Daltons and is non-antigenic (1, 2, 3), and non-pyrogenic.

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Healon® EndoCoat Ophthalmic Viscosurgical Device

Healon® OVD demonstrated non-inferiority compared to Viscoat® OVD in corneal endothelial cell count (ECC) from preoperative to three months postoperative (p=0.0001, 1-sided t-test, n = 54). The observed mean percent changes in ECC from preoperative to three months postoperative for Healon® OVD and Viscoat® OVD were -4.7% and -7.5%, respectively, with a 2.3% percentage point difference (90% CI: -2.23%, 4.35%).

The distribution of postoperative medical findings/observations was similar between the two study groups and within the range of what would typically be reported. In the early postoperative period, inflammatory cells in the anterior chamber were the most reported form of inflammation for both viscoelastic groups. Reports of inflammatory cells diminished over time by minimal levels by the three-month visit in both viscoelastic groups. Early postoperative incidence rates of corneal, epithelial, and stromal edema were low with similar results in both groups, diminishing over time. For other general slit-lamp findings, the majority of subjects in both groups were reported as “none” at all postoperative visits.

Clinical Trial Adverse Events

Safety Population

Thirty-nine subjects experienced adverse events in the study. None of the adverse events were considered unanticipated. Ninety-two percent of the adverse events were IOP ≥30 mm Hg. Incidence of IOP ≥30 mm Hg occurred at a rate of 10.5% in the Healon® OVD Group and 7.5% in the Viscoat® OVD group. The three adverse events not related to IOP ≥30 mm Hg include: one subject in the Healon® OVD Group who developed cystoid macular edema (CME) requiring treatment and two subjects in the Viscoat® OVD group; one who underwent lens implantation in the eye due to a dense capsul and another who had an intraocular foreign body removed from the study eye. None of these three events was considered by the investigators to be related to the viscoelastic used.

Safety Population

Operative Parameters - Removal of Viscosurgical agent

**Table 1: Average Viscoelastic Removal Times**

<table>
<thead>
<tr>
<th>Viscosurgical Removal</th>
<th>Healon® OVD</th>
<th>Viscoat® OVD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>149.1</td>
<td>133.2</td>
</tr>
<tr>
<td>SD</td>
<td>37.82</td>
<td>35.21</td>
</tr>
<tr>
<td>Median</td>
<td>175.0</td>
<td>121.0</td>
</tr>
<tr>
<td>Min</td>
<td>60</td>
<td>60</td>
</tr>
<tr>
<td>Max</td>
<td>106</td>
<td>454</td>
</tr>
</tbody>
</table>

Safety Population

Operative Parameters - Removal of Viscosurgical agent

**Table 2: Ease of Viscosurgical Removal (n of cases)**

<table>
<thead>
<tr>
<th>Ease of Removal</th>
<th>Healon® OVD</th>
<th>Viscoat® OVD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Easy</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>Average</td>
<td>156</td>
<td>142</td>
</tr>
<tr>
<td>Difficult</td>
<td>86</td>
<td>49</td>
</tr>
<tr>
<td>Very Difficult</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

HOW SUPPLIED

Healon® EndoCoat OVD is a sterile, non-lyophilized preparation supplied in a disposable single-use glass syringe, delivering 0.6 mL of a solution of sodium hyaluronate in a pharmaceutical buffered salt solution.

A sterile, single-use 25-gauge, disposable, bent, blunt-tip thin-wall cannula and cannula guard are provided within the package. The cannula sheath should be used to firmly attach the cannula to the syringe. Contents of unused and undamaged blister package are sterile. Do not use if package is opened or damaged.

Contents

Each ml of Healon® EndoCoat OVD contains:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Contents per ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>sodium hyaluronate</td>
<td>30.00 mg</td>
</tr>
<tr>
<td>sodium chloride</td>
<td>0.24 mg</td>
</tr>
<tr>
<td>potassium chloride</td>
<td>0.56 mg</td>
</tr>
<tr>
<td>calcium chloride</td>
<td>0.36 mg</td>
</tr>
<tr>
<td>magnesium chloride</td>
<td>0.24 mg</td>
</tr>
<tr>
<td>sodium acetate</td>
<td>2.92 mg</td>
</tr>
<tr>
<td>sodium citrate</td>
<td>1.26 mg</td>
</tr>
<tr>
<td>sodium phosphate dibasic</td>
<td>0.42 mg</td>
</tr>
<tr>
<td>sodium phosphate monobasic</td>
<td>0.06 mg</td>
</tr>
<tr>
<td>water for injection</td>
<td>as required</td>
</tr>
</tbody>
</table>

REFERENCES

5. Caution: Federal (USA) law restricts this device to sale, distribution, or use by or on the order of a physician.

PRODUCT OF USA

1. Remove plastic tip cap from syringe tip.
2. Thread the 25 gauge cannula onto the syringe and confirm that it is firmly seated.
3. Remove the plastic sheath from the cannula by pulling it away in a straight motion. Ensure that cannula remains fully seated to syringe.
4. Guide the cannula needle through the opening of the cannula guard provided until the cannula guard is fully seated against the cannula hub.
5. Click the cannula guard in place around the syringe.
6. Siphery Orientation: Hold the syringe with the opening of the finger grip (backstop) facing the palm; rotate syringe body within the finger grip to achieve desired cannula positioning.