Connect the cannula and check for proper function. A sterile single-use, 25 gauge cannula is included with each syringe.

Preparation and Storage

Refrigerated Healon® should be held at room temperature for approximately 30 minutes before use. Store between 2° to 8°C (35° to 47°F).

Healon® syringes are terminally steam sterilized and aseptically packaged.

Sterile opening technique

Press the vial completely into the holder so that the needle perforates the membrane.

Assembly

Screw the plastic rod into the blue plunger.

Remove the plastic rod.

Connect the cannula and check for proper function.

Store at 2 to 8°C (35 to 47°F).

For single use only.

References


The difference in percent change in endothelial cell counts between the Healon® and Healon group has been investigated in another clinical study. The endothelial cell count evaluation included 81 patients in the Healon® group and 78 in the Healon group. The mean age in the Healon® group was 69.9 years and in the Healon group 68.9 years.

No difference was observed between the treatment groups with regard to the change from pre-operative values to the values determined at 3 months after surgery. The percentage cell loss in the Healon® group was 9.4% and in the Healon group 11.2%.

Table 6. Adverse Events. Number of patients in whom a medical event occurred at least once. All randomized qualified patients.

Table 7. Endothelial cell counts, changes and percentage change in endothelial cell counts from pre-surgery at 3 months after surgery. The percentage cell loss in the Healon® group was 9.4% and in the Healon group 11.2%.

Table 5. Number of patients with iritis. All randomized qualified patients.

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**Important**

Puncture the membrane before screwing on the plastic rod.

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There was no difference seen between the two groups with regard to the mean Precautions

(preoperative) intraocular pressure and complications in surgical procedures also may lead to increased intraocular pressure, consequently, extra care should be taken in patients with these conditions. Phystostigmin lowering treatment should always be considered and especially in cases where Healon5 has to be left in the eye for clinical reasons.

Both the Rock’s Roll technique and the “Behind the Lens” or the Two Compartment Technique (TCT) were evaluated during the clinical trial. The table below reflects IOPs at 30 min to 5 hours postoperatively in association with removal technique.

<table>
<thead>
<tr>
<th>Group</th>
<th>IOP</th>
<th>MEAN</th>
<th>SD</th>
<th>UP 7 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-surgery</td>
<td>24 hours</td>
<td>48 hours</td>
<td>2 weeks</td>
<td></td>
</tr>
<tr>
<td>Healon5</td>
<td>15.4</td>
<td>21.2</td>
<td>18.5</td>
<td>17.3</td>
</tr>
<tr>
<td>IOP</td>
<td>2.9</td>
<td>7.2</td>
<td>6.1</td>
<td>5.1</td>
</tr>
<tr>
<td>MAX</td>
<td>29</td>
<td>36</td>
<td>32</td>
<td>30</td>
</tr>
</tbody>
</table>

Table 3. IOP monitoring during the study. All randomized qualified patients.

Healon5® is a sterile, non-pyrogenic, transparent viscoelastic preparation of a highly purified, noninflammatory, high molecular weight (average molecular weight 4 million) sodium hyaluronate. Healon5 contains 23 mg/ml of sodium hyaluronate 5000, dissolved in repeating disaccharide units of N-acetylglucosamine and sodium glucuronate linked by glucosidic bonds. Sodium hyaluronate is a physiological substance that is widely distributed in the extracellular matrix of connective tissues in both animals and man. For example, it is present in the vitreous and aqueous humor of the eye, the synovial fluid, the skin, and the umbilical cord. Sodium hyaluronates derived from various human or animal tissues do not differ chemically.

The fraction of sodium hyaluronate in Healon5 is reported to be nonantigenic13 and does not cause inflammatory or foreign body reactions.

The graph below represents the flow curve (shear viscosity versus shear rate). The viscosity of Healon at rest (at zero shear rate) is about 7 million mPas, a viscosity higher than Healon and Healon 50. At high shear rates, such as during injection, the viscosity of Healon5 decreases dramatically due to high pseudoplasticity, facilitating injection through a 25G needle.

As a result of clinical experience, the following removal technique (TCT) is recommended to ensure efficient removal of Healon5. Use a standard 14G tip, 0.3 mm in length, with effective flow of 20-25 ml/min and vacuum of 250-300 mmHg with a potential maximum setting at 500 mmHg. When using a machine with a periodic pulse, use the upper limits of the suggested settings. When using a Venturis pump use the lower limits of the suggested settings. Bottle height should be 60-70 cm above eye level.

1. Start the removal directly after the end of the IOL implantation, while the anterior chamber is still filled with Healon5 and before the IOL has been centered. Go behind the IOL optic without engaging the iris plane and then start flow. Remove Healon5 from the capsular bag first and ensure that the lens has adequately centered. During removal of Healon5 from the capsular bag, the continuous flow of irrigation fluid keeps the bag inflated and reduces the risk of aspirating the capsular bag. While maintaining continuous flow remove the tip from behind the optic and place it on top of the optic.

2. Continue the removal by circling the I/A tip at the iris plane, or on the optic surface, then make an additional sweep in the anterior chamber paying particular attention to the angles. An alternative technique to remove Healon5 is to create maximum turbulence to make Healon5 fracture into large pieces by using the Rock’s Roll technique (described below) with standard 14G tip, 0.3 mm, with high settings, flow rates should be 25-30 ml/min and vacuum 150-200 mmHg, depending on the type of pump. If a peristaltic pump is used, the vacuum should be set towards the higher limit.

If a venturi pump is used, the vacuum should be set towards the lower limit. Bottle height should be 60-70 cm above eye level. Today’s phaco machines often use linear control. The suggested machine settings can only be achieved if the surgeon operates the phaco machine with fully depressed foot pedal.

If a venturi pump is used, the vacuum should be set towards the lower limit. Bottle height should be 60-70 cm above eye level. Today’s phaco machines often use linear control. The suggested machine settings can only be achieved if the surgeon operates the phaco machine with fully depressed foot pedal.

The viscosity of Healon5 at rest (at zero shear rate) is about 7 million mPas, a viscosity higher than Healon and Healon 50. At high shear rates, such as during injection, the viscosity of Healon5 decreases dramatically due to high pseudoplasticity, facilitating injection through a 25G needle.