You have the hands of a surgeon and the eyes of an artist. That's why your VISCOELASTIC is HEALON®. Trust the HEALON® OVDs to support your craft and provide premium protection for patient eyes throughout the cataract surgery.
HEALON® OVDs...
ONE COMPLETE SOLUTION

Artfully balance science and skill with the protection, control, and ease of use that define the HEALON® Family of OVDs

<table>
<thead>
<tr>
<th>Classification</th>
<th>HEALON® PRO</th>
<th>HEALON GV® PRO</th>
<th>HEALON® PRO</th>
<th>HEALON EndoCoat®</th>
<th>HEALON Duet® PRO Dual Pack*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composition</td>
<td>Cohesive</td>
<td>Cohesive**</td>
<td>Viscoadaptive</td>
<td>Dispersive</td>
<td>Cohesive</td>
</tr>
<tr>
<td></td>
<td>10 mg/mL</td>
<td>18 mg/mL</td>
<td>23 mg/mL</td>
<td>30 mg/mL</td>
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<tr>
<td></td>
<td>(1% HA)</td>
<td>(1.8% HA)</td>
<td>(2.3% HA)</td>
<td>(3% HA)</td>
<td>(1% HA)</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>3,200,000 Daltons</td>
<td>3,200,000 Daltons</td>
<td>3,200,000 Daltons</td>
<td>800,000 Daltons</td>
<td>3,200,000 Daltons</td>
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<tr>
<td>Viscosity</td>
<td>150,000 mPas</td>
<td>2,000,000 mPas</td>
<td>4,000,000 mPas</td>
<td>50,000 cps</td>
<td>150,000 mPas</td>
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<tr>
<td>Fill Size</td>
<td>0.55 mL, 0.85 mL</td>
<td>0.85 mL</td>
<td>0.6 mL</td>
<td>0.85 mL</td>
<td>0.55 mL</td>
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<tr>
<td>Storage Temperature</td>
<td>+2°C to +8°C</td>
<td>+2°C to +8°C</td>
<td>+2°C to +8°C</td>
<td>+2°C to +25°C</td>
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<tr>
<td>SKU:</td>
<td>0.55 mL 10240011, 0.85 mL 10240012</td>
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<td>VT585U</td>
<td>10240016</td>
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</table>

All HEALON® OVDs are not made with natural rubber latex.

**HEALON Duet® PRO OVD includes HEALON EndoCoat® OVD (0.85 ml) and HEALON® PRO OVD (0.55 ml).

**HEALON GV PRO is a high viscosity cohesive OVD that displays dispersive behavior during removal.

For healthcare professionals only. Please read the Directions for Use for Important Safety Information and consult our specialists if you have any questions.

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REFERENCES

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR HEALON® FAMILY OF PRODUCTS

Rx ONLY

INDICATIONS FOR HEALON EndoCoat® OVD: HEALON EndoCoat® OVD is an ophthalmic viscoelastic containing 3% sodium hyaluronate indicated for use as a surgical aid in patients undergoing ophthalmic anterior segment procedures including: Cataract surgery with an intraocular lens, Cataract surgery without an intraocular lens, Secondary intraocular lens implantation, Anterior segment surgery, Phacoemulsification surgery, Transconjunctival surgery, and other intraocular surgeries.*

INDICATIONS FOR HEALON® PRO OVD: The HEALON® PRO OVD is indicated for use as a surgical aid in cataract extraction intra- and extracapsular, IOL implantation, corneal transplant procedures, and other anterior segment surgeries.**

INDICATIONS FOR HEALON® GV PRO OVD: The HEALON® GV PRO OVD serves to maintain a deep anterior chamber during surgery, allows for efficient manipulation with less trauma to the cornеal endothelium and other surrounding tissues. Furthermore, its viscoelasticity helps to push back the vitreous face and prevent formation of a postoperative flat chamber. In posterior segment surgery the HEALON® PRO OVD serves as a surgical aid in gently separate, maneuver and hold tissues. The HEALON® PRO OVD creates a clear field of vision thereby facilitating infra- and post-operative inspection of the retina and phacoemulsiﬁcation.

INDICATIONS FOR HEALON® GV PRO OVD: The HEALON® GV PRO OVD is intended for use in anterior segment ophthalmic surgical procedures of the human eye. The HEALON® GV PRO OVD is designed to create and maintain a deep anterior chamber which facilitates manipulation inside the eye with reduced trauma to the corneal endothelium and other ocular tissues. The HEALON® GV PRO OVD can also be used to efficiently separate and control ocular tissues. The HEALON® GV PRO OVD is not designed to have any pharmacological effect.

INDICATIONS FOR HEALON® PRO OVD: The HEALON® PRO Ophthalmic Viscoelastic Device [OVD] is intended for use in anterior segment ophthalmic surgical procedures of the human eye. The HEALON® PRO OVD is designed to create and maintain a deep anterior chamber which facilitates manipulation inside the eye with reduced trauma to the corneal endothelium and other ocular tissues. The HEALON® PRO OVD can also be used to efficiently separate and control ocular tissues.

CONTRAINDICATIONS: There are no known contraindications to the use of HEALON® Family of OVDs when used as recommended.

WARNINGS: HEALON® GV PRO OVD is different compared to the similarly named Healon® GV OVD. Adequate removal of Healon® GV OVD may require the specific surgical removal techniques described below. Users should weigh the potential benefit/risk ratio of using this device based on their own personal skill and comfort level with the recommended surgical removal techniques. The HEALON® EndoCoat® OVD delivery system is not designed or intended to be attached to instruments other than the one provided with the product, as it may cause cannula detachment. When using HEALON® EndoCoat® OVD for surgery, the eye should not be irrigated with any solution containing benzalkonium chloride, because the mixing of quaternary ammonium salts, such as benzalkonium chloride, with sodium hyaluronate results in the formation of a precipitate and reduces the efficacy of the product.

PRECAUTIONS FOR THE HEALON® FAMILY OF PRODUCTS: The OVD may appear cloudy or form precipitates when it is injected. Should it be observed, remove the cloudy or precipitated material by irrigation and/or aspiration. Use only if the HEALON® OVD solution is clear. Postoperative intraocular pressure [IOP] may be increased if the HEALON® OVDs are left in the eye. The potential for early and short-term post-operative IOP spikes exists with HEALON® GV OVDs. In the HEALON® PRO OVD, HEALON® GV PRO OVD, or HEALON® GV OVD, postoperative IOP spikes can occur due to the water content of the fluid. The IOP spikes may be released when the syringe diaphragm is punctured. Postoperative intraocular pressure may also be elevated as a result of preexisting glaucoma, compromised outflow and by operative procedures and sequelae thereto, including enzymatic zonulysis, absence of an iridectomy, trauma to filtration structures, and by blood and lenticular remnants in the anterior chamber. Do not orbit the eye chambers with the HEALON® OVDs, completely remove the HEALON® OVDs by irrigation and/or aspiration at the close of the surgery, and fully monitor intraocular pressure, particularly during the postoperative period. Treat with appropriate intraocular pressure lowering therapy, if required. Overfilling the anterior or posterior segment of the eye with the HEALON® PRO OVD, may cause increased intraocular pressure, glaucoma, or other ocular damage. Pre-existing glaucoma, other causes of compromised outflow, higher preoperative intraocular pressure and complications in surgical procedures may also lead to increased intraocular pressure; therefore, extra care should be taken in patients with these conditions as described in the HEALON® OVDs Directions for Use. HEALON® PRO OVD, HEALON® GV PRO OVD and HEALON® GV PRO OVD are a highly puriﬁed fraction extracted from microbial fermentation which may contain minute amounts of protein. The physician should be aware of the potential allergic risks such as postoperative inﬂammation that can occur with injection of biological materials.

PRECAUTIONS FOR HEALON® GV PRO OVD: Injection of the HEALON® GV PRO OVD creates pressure in the syringe. To prevent expulsion of the cannula into the eye, ensure that the plunger is securely attached to the plunger hub. Use of the spring clamp is recommended. Extrusion of a test droplet is recommended prior to entering the eye, and excessive force on the plunger should be avoided. HEALON® EndoCoat® OVD does not require refrigeration. If refrigerated, HEALON® EndoCoat® OVD should be allowed to attain room temperature prior to use.

PRECAUTIONS FOR HEALON® PRO OVD: As a result of non-clinical and clinical experience, during removal, HEALON® GV PRO OVD performs similarly to Healon® GV and Healon® GV PRO OVDs, two high-viscosity OVDs that are more difﬁcult to remove from the eye compared to typical cohesive OVDs. Two surgical removal techniques were previously studied with the original Healon® GV OVD and were shown to be effective at removing Healon® GV OVD from the eye; The Behind the Lens or the Two-Compartment Technique (TCT) was demonstrated in a clinical study. The TCT was accomplished by using the Rock'n Roll technique described below with standard I/A tip, 0.3 mm, with effective ﬂow of 30-35 ml/min and vacuum of 250-300 mmHg with a potential maximum setting at 500 mmHg. When using a machine with a peristaltic pump, the following two surgical techniques are recommended to remove Healon® GV PRO OVD from the eye. The safety and effectiveness of other removal techniques have not been demonstrated in a clinical study. The following two surgical techniques (Behind the Lens or TCT) is one option to ensure removal of the HEALON® GV PRO OVD. Use a standard I/A tip, 0.3 mm, with effective ﬂow of 30-35 ml/min and vacuum of 250-300 mmHg with a potential maximum setting at 500 mmHg. When using a machine with a peristaltic pump, set the maximum vacuum pressure to 350-500 mmHg, depending on the type of pump. If a peristaltic pump is used, the vacuum should be set towards the upper limit. If a Venturi pump is used, the vacuum should be set towards the lower limit. Set the I/A tip just above the 60-70 cmH2O level. For phacoemulsification machines that use linear foot pedal control, the suggested settings can only be achieved if the surgeon operates the phacoemulsification machine with fully depressed foot pedal. Settings will vary according to user preference for different types of programmable foot pedals. Start by circling the hand piece in the anterior segment at iris plane. Gently rest the I/A hand piece on the anterior surface of the optic. Press on the I/A hand piece directing the flow into the bubble and the hand piece towards the posterior of the capsular bag and stay in this position for a few seconds and then repeat on the other side of the IOL optic until the HEALON® GV PRO OVD is completely removed. Finally, sweep the anterior chamber including the angles. Note: The above phacoemulsification machine settings were used in a Healon® GV OVD clinical study. Individual phacoemulsification system parameters vary. Although phacoemulsification machine settings may need to be altered due to differences in phacoemulsification machine technology, only the machine settings that are described above were shown to be effective at removing HEALON® GV OVD in a clinical study. The safety and effectiveness of other phacoemulsification machine settings have not been demonstrated in a clinical study.

SERIOUS ADVERSE EVENTS: The most frequently reported serious adverse events that occurred during the clinical trial of the HEALON® PRO were intraocular pressure [IOP] spikes x30 mmHg [18 eyes, 8.5%] and surgical reinsertion [AC Taps to treat the elevated IOP, 7 eyes, 3.3%].

In the HEALON® GV OVD study, ninety-two percent of the adverse events were IOP >30 mmHg; incidence of IOP >30 mmHg occurred at a rate of 10.5%. One subject in the HEALON® GV PRO OVD group developed cystoid macular edema [CME] requiring treatment. This event was not considered by the investigators to be related to the viscoelastic used.

ATTENTION: Reference the Directions for Use for a complete listing of Important Indications and Safety Information.