HEALON ENDOCOAT®

Premium protection for patients' eyes so you can focus on your craft

To preserve the eye's integrity during procedures, HEALON EndoCoat® dispersive OVD:

- Maintains anterior chamber, protects the corneal endothelium and other ocular tissue during cataract surgery[1]
- Is clear and transparent to afford you a more functional view during procedures

Johnson&Johnson VISION

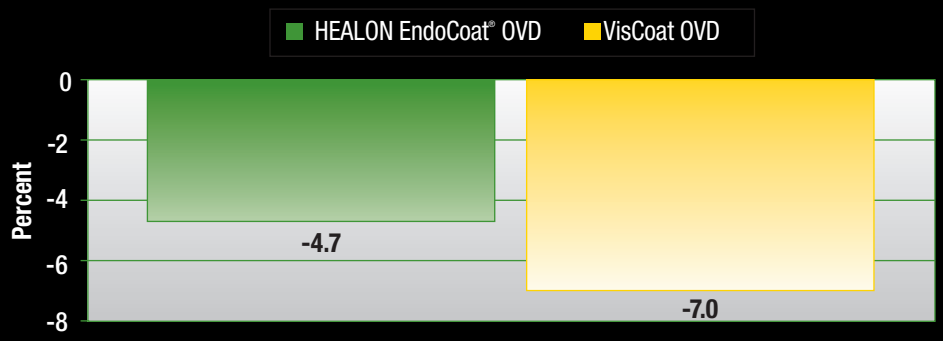
Healon® FAMILY of OVDs

HEALON ENDOCOAT®

- A low molecular weight allows **HEALON EndoCoat®** OVD to remain in the anterior chamber, ensuring **protection** of endothelial cells throughout the entire phaco process[1]
- **Total clarity** is maintained throughout the surgical field[1]

Refrigeration NOT required

Mean endothelial cell density loss from preoperative to 3 months postoperative[1]



FEATURE	HEALON EndoCoat® OVD
CANNULA SIZE	25 gauge
PRODUCT VOLUME	0.85 mL
CANNULA GUARD	Yes
DELIVERY SYSTEM	Improved ergonomics
VISCOSITY	50,000 cps

FEATURE	HEALON EndoCoat® OVD
STORAGE CONDITIONS	36°F to 77°F (2°C to 25°C) *Refrigeration not required*
APPEARANCE	Clear, colorless viscous solution
COMPOSITION	3% sodium hyaluronate
MOLECULAR WEIGHT	Approximately 800,000 Da

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR Healon EndoCoat® OVD

Rx Only

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

INDICATIONS

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. Healon EndoCoat OVD maintains a deep chamber during anterior segment surgery, aids in tissue manipulation during surgery, enhances visualization during the surgical procedure and protects the corneal endothelium and other ocular tissue. The viscoelasticity of the solution maintains the normal position of the vitreous face and prevents formation of a flat chamber during surgery. It may also be used to coat intraocular lenses and insertion instruments prior to intraocular 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 results 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 during surgery.

PRECAUTIONS

CAUTIONS: To prevent expulsion of the cannula into the eye, ensure that the cannula is securely attached to the fitting on the syringe. Use of the cannula guard is recommended. Over tightening may cause the hub to weaken and possibly detach from the syringe. Excessive force on the plunger should be avoided. Product and cannula are for single use only. Re-use may cause eye inflammation. The potential for early and short-term postoperative intraocular pressure (IOP) spikes exists with dispersive OVDs, which potentially require more time and care to remove from the eye. Therefore, it is recommended that Healon Endocoat OVD be removed from the eye completely by irrigating and aspirating with sterile irrigation solution to reduce the risk of early postoperative IOP spikes. Pre-existing glaucoma, the surgery itself, or retained viscoelastic (particularly in patients with compromised trabecular meshwork) can cause increased intraocular pressure after the procedure. The intraocular pressure of postoperative patients should be carefully monitored, particularly in the early post operative period. Remove Healon EndoCoat OVD completely from the anterior chamber at the end of the procedure. Corrective therapy should be initiated if the postoperative intraocular pressure rises above safe levels. Use only if solution is clear. Do not use in cases of known hypersensitivity to any of the ingredients of this product. If refrigerated, Healon EndoCoat OVD should be allowed to attain room temperature prior to use.

ADVERSE EVENTS

During the clinical trial, elevated intraocular pressure ≥ 30 mmHg occurated at a rate of 10.5% in the Healon EndoCoat OVD group, and treatment of cystoid macular edema (CME) occurred at a rate of 0.5%.

REFERENCES

1. HEALON EndoCoat® Dispersive OVD [package insert]. Santa Ana, Calif: Johnson & Johnson Vision Inc.

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

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