

**Adverse events**

Increased intraocular pressure has been reported after use of the Healon GV OVD:

- Increased intraocular pressure is likely to occur if the Healon GV OVD is not removed as completely as possible. Clinical judgement concerning the use of this product should be considered in cases where thorough removal may not be possible. The Precautions noted above should be taken to manage any increased postoperative intraocular pressure and to reduce the likelihood of occurrence of related postoperative complications such as optic neuropathy, pupillary atonia and dilation, and iris atrophy.

Rarely, postoperative inflammatory reactions (iritis, hypopyon, endophthalmitis) following the use of sodium hyaluronate, as well as incidents of corneal edema and corneal decompensation, have been reported. Their relationship to sodium hyaluronate has not been established.

**How supplied**

The Healon GV OVD is a sterile, non-pyrogenic, viscoelastic preparation supplied in disposable 0.85 mL and 0.55 mL glass syringes. Each mL of the Healon GV OVD contains:

- 14 mg sodium hyaluronate 7000
- 8.5 mg sodium chloride
- 0.28 mg disodium hydrogen phosphate dihydrate
- 0.04 mg sodium dihydrogen phosphate dihydrate
- q.s. water for injection USP

The Healon GV OVD syringes are terminally sterilized and aseptically packaged.

A sterile single-use, 27 gauge cannula is included with each syringe.

**Preparation and storage**

Refrigerated Healon GV OVD should be held at room temperature for approximately 30 minutes before use. Protect from freezing and exposure to light.

For intraocular use.

Store between 2 to 8°C (36 to 46°F).

**Definition of symbols on cannula, syringe-, blister label and carton.**

	Caution, see instructions for use
	See instructions for use
	Do not reuse
	Protect from light
	Do not use if the packaging has been opened or damaged
	Protect from freezing
	Temperature limitation
	Sterilized using steam
	Sterilized by ethylene oxide
	Manufacturer
	Batch code
	Use by (YYYY-MM : year month)
	Latex Free
	Catalogue number

**References**

1. Balazs, E.A.: Ultrapure hyaluronic acid and the use thereof. U.S. patent 4,141,973 (1979)
2. Fry L.L. & Yee R.W. (1993): Healon GV in extracapsular cataract extraction with intraocular lens implantation. Cataract Refract. Surg. 19:409-412.
3. Gaskel A. & Haining W. (1991): A double blind randomized multicentre clinical trial of "Healon GV," compared with "Healon" in ECCE with IOL implantation. Eur J. Implant Ref. Surg. 3:241.

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Sodium Hyaluronate

**LATEX FREE**

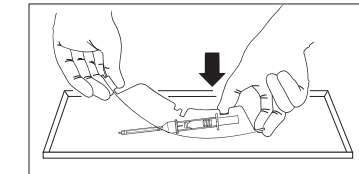
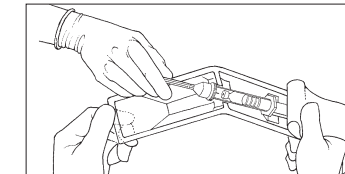
**Instructions**

**Sterile opening technique**

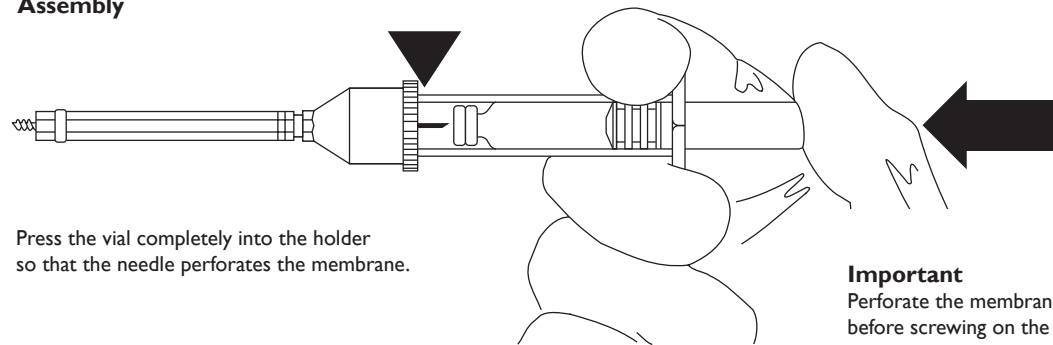
Tear off the paper covering.

Bend the plastic backwards at the central indentation so as to fully expose the white plastic rod.

Dislodge syringe and place onto sterile field.

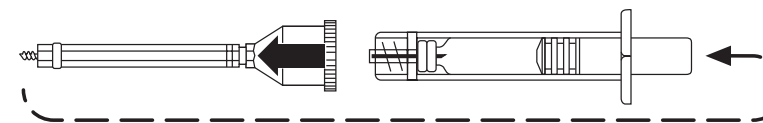


**Assembly**

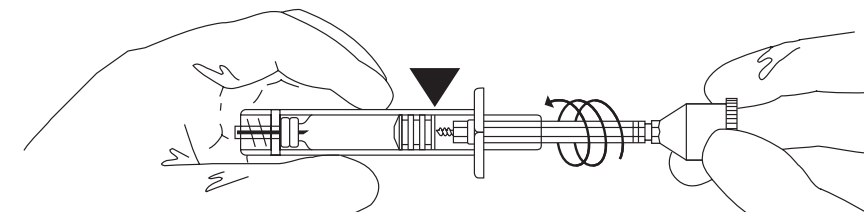


Press the vial completely into the holder so that the needle perforates the membrane.

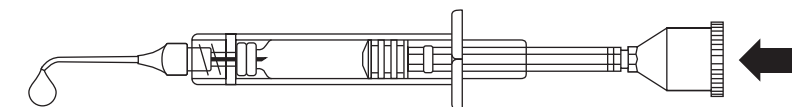
**Important**  
Perforate the membrane before screwing on the plastic rod.



Remove the plastic rod.



Screw the plastic rod into the blue plunger.



Connect the cannula and check for proper function.

**Store at 2 to 8°C (36 to 46°F).**

**For single use only**



# Healon®

## Sodium Hyaluronate

### Product information

#### Description

The Healon® Ophthalmic Viscosurgical Device (OVD) is a sterile, nonpyrogenic, viscoelastic preparation of a highly purified, noninflammatory, high molecular weight fraction of sodium hyaluronate. The Healon OVD contains 10 mg/mL of sodium hyaluronate dissolved in physiological sodium chloride phosphate buffer (pH 7.0-7.5). This high molecular weight polymer is made up of repeating disaccharide units of N-acetyl-glucosamine and sodium glucuronate linked by β 1-3 and β 1-4 glycosidic bonds.

#### Characteristics

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 prepared from various human and animal tissues are not chemically different from each other.

The Healon OVD is a specific fraction of sodium hyaluronate developed as an ophthalmosurgical aid for use in anterior segment and vitreous procedures. It is specific in that:

1. It has a high molecular weight.
2. It is reported to be nonantigenic<sup>1,6</sup>.
3. It does not cause inflammatory<sup>2</sup> or foreign body reactions.
4. It has a high viscosity.

Furthermore, the 1% solution of the Healon OVD is transparent, is reported to remain in the anterior chamber for less than 6 days<sup>3</sup> and protects corneal endothelial cells<sup>4,5</sup> and other ocular structures. The Healon OVD does not interfere with epithelialization and normal wound healing.

#### Uses

The Healon OVD is indicated for use as a surgical aid in cataract extraction (intra- and extracapsular), IOL implantation, corneal transplant, glaucoma filtration and retinal attachment surgery.

In surgical procedures in the anterior segment of the eye, instillation of the Healon OVD serves to maintain a deep anterior chamber during surgery, allowing for efficient manipulation with less trauma to the corneal 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 OVD serves as a surgical aid to gently separate, maneuver and hold tissues. The Healon OVD creates a clear field of vision thereby facilitating intra- and post-operative inspection of the retina and photocoagulation.

#### Contraindications

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

#### Precautions

Those normally associated with the surgical procedure being performed.

Overfilling the anterior or posterior segment of the eye with the Healon OVD may cause increased intraocular pressure, glaucoma, or other ocular damage.

Postoperative intraocular pressure may also be elevated as a result of pre-existing 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. Since the exact role of these factors is difficult to predict in any individual case, the following precautions are recommended:

- Don't overfill the eye chambers with the Healon OVD (except in glaucoma surgery - See Applications section).
- In posterior segment procedures in aphakic diabetic patients special care should be exercised to avoid using large amounts of the Healon OVD.
- Remove some of the Healon OVD by irrigation and/or aspiration at the close of surgery (except in glaucoma surgery - See Applications section).
- Carefully monitor the intraocular pressure, especially during the immediate postoperative period. If significant rises are observed, treat with appropriate therapy.

Care should be taken to avoid trapping air bubbles behind the Healon OVD.

Because the Healon OVD is a highly purified fraction extracted from avian tissues and is known to contain minute amounts of protein, the physician should be aware of potential risks of the type that can occur with the injection of any biological material.

Because of reports of an occasional release of minute rubber particles, presumably formed when the diaphragm is punctured, the physician should be aware of this potential problem. Express a small amount of the Healon OVD from the syringe prior to use, and carefully examine the remainder as it is injected.

Reprocessed cannulas should not be used.

Sporadic reports have been received indicating that the Healon OVD may become "cloudy" or form a slight precipitate following instillation into the eye. The clinical significance of these reports, if any, is not known since the majority received to date do not indicate any harmful effects on ocular tissues. The physician should be aware of this phenomenon and, should it be observed, remove the cloudy or precipitated material by irrigation and/or aspiration.

*In vitro* laboratory studies suggest that this phenomenon may be related to interactions with certain concomitantly administered ophthalmic medications.

Use only if solution is clear.

#### Adverse reactions

The Healon OVD is extremely well tolerated after injection into human eyes. A transient rise of intraocular pressure postoperatively has been reported in some cases.

In posterior segment surgery intraocular pressure rises have been reported in some patients, especially in aphakic diabetics, after injection of large amounts of the Healon OVD.

Rarely, postoperative inflammatory reactions (iritis, hypopyon) as well as incidents of corneal edema and corneal decompensation have been reported. Their relationship to the Healon OVD has not been established.

#### Applications

Cataract surgery - IOL implantation

A sufficient amount of the Healon OVD is slowly, and carefully introduced (using a cannula or needle) into the anterior chamber.

Injection of the Healon OVD can be performed either before or after delivery of the lens. Injection prior to lens delivery will, however, have the additional advantage of protecting the corneal endothelium from possible damage arising from the removal of the cataractous lens<sup>5</sup>. The Healon OVD may also be used to coat surgical instruments and the IOL prior to insertion.

Additional Healon OVD can be injected during surgery to replace any Healon OVD lost during surgical manipulation (see Precautions section).

Glaucoma filtration surgery

In conjunction with performing of the trabeculectomy, the Healon OVD is injected slowly and carefully through a corneal paracentesis to reconstitute the anterior chamber. Further injection of the Healon OVD can be continued allowing it to extrude into the subconjunctival filtration site and through and around the sutured outer scleral flap.

Corneal transplant surgery

After removal of the corneal button, the anterior chamber is filled with the Healon OVD. The donor graft can then be placed on top of the bed of Healon OVD and sutured in place. Additional Healon OVD may be injected to replace the Healon OVD lost as a result of surgical manipulation (see Precautions section). The Healon OVD has also been used in the anterior chamber of the donor eye prior to trepanation to protect the corneal endothelial cells of the graft<sup>5</sup>.

Retinal attachment surgery

The Healon OVD is slowly introduced into the vitreous cavity. By directing the injection, the Healon OVD can be used to separate membranes (e.g. epiretinal membranes) away from the retina for safe excision and release of traction. The Healon OVD also serves to maneuver tissues into the desired position, e.g. to gently push back a detached retina or unroll a retinal flap, and aids in holding the retina against the sclera for reattachment.

#### How supplied

The Healon OVD is a sterile, nonpyrogenic, viscoelastic preparation supplied in disposable glass syringes, delivering 0.85 mL, 0.55 mL or 0.4 mL sodium hyaluronate (10 mg/mL) dissolved in physiological sodium chloride phosphate buffer (pH 7.0-7.5). Each mL of Healon OVD contains 10 mg of sodium hyaluronate, 8.5 mg sodium chloride, 0.28 mg of disodium hydrogen phosphate dihydrate, 0.04 mg of sodium dihydrogen phosphate dihydrate and q.s. water for injection U.S.P. The Healon OVD syringes are terminally sterilized and aseptically packaged.

A sterile single-use 27 G cannula is enclosed in the 0.4 mL, 0.55 mL, and 0.85 mL boxes.

Refrigerated Healon OVD should be allowed to attain room temperature (approximately 30 minutes) prior to use.

For intraocular use.

Store at 2 to 8°C (36 to 46°F).















Protect from freezing.

Protect from light.

#### Caution

Federal law restricts this device to sale by or on the order of a physician.


#### Definition of symbols on cannula, syringe-, blister label and carton.

	Caution, see instructions for use
	See instructions for use
	Do not reuse
	Protect from light
	Do not use if the packaging has been opened or damaged
	Protect from freezing
	Temperature limitation
	Sterilized using steam
	Sterilized by ethylene oxide
	Manufacturer
	Batch code
	Use by (YYYY-MM : year month)
	Latex Free
	Catalogue number

#### References

1. Richter, W., Ryde, M. & Zetterström, O.: Nonimmunogenicity of a purified sodium hyaluronate preparation in man. *Int Arch Appl Immun* 59:45-48 (1979).
2. Balazs, E.A.: Ultrapurified hyaluronic acid and the use thereof. U.S. Patent 4, 141, 973 (1979).
3. Balazs, E.A., Miller, D & Stegmann, R.: Viscosurgery and the use of Na-hyaluronate in intraocular lens implantation. *Lecture, Cannes, France (1979)*.
4. Miller, D. & Stegmann, R.: Use of Na-hyaluronate in anterior segment eye surgery. *Am Intra-Ocular Implant Soc J* 6 (1980b) p 13-15.
5. Pape, L.G. & Balazs, E.A.: The use of sodium hyaluronate (Healon®) in human anterior segment surgery. *Ophthalmol* 87 (1980) p 699-705.
6. Richter, W.: Non-immunogenicity of purified hyaluronic acid preparations tested by passive cutaneous anaphylaxis. *Int Arch All* 47 (1974) p 211-217.

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# Healon GV®

## Sodium Hyaluronate

### Product information

#### Description

The Healon GV® Ophthalmic Viscosurgical Device (OVD) is a sterile, non-pyrogenic, transparent viscoelastic preparation of a highly purified, noninflammatory, high molecular weight (average = 5 million daltons) fraction of sodium hyaluronate. The Healon GV OVD contains 14 mg/mL of sodium hyaluronate 7000, dissolved in a physiological sodium chloride phosphate buffer (pH 7.0-7.5). This polymer consists of repeating disaccharide units of N-acetylglucosamine and sodium glucuronate linked by glycosidic 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.

#### Indications

The Healon GV OVD is indicated for use in anterior segment ophthalmic surgical procedures.

The Healon GV OVD creates and maintains a deep anterior chamber, to facilitate manipulation inside the eye with reduced trauma to the corneal endothelium and other ocular tissues. The Healon GV OVD also can be used to efficiently maneuver, separate and control ocular tissues.

#### Contraindications

There are no known contraindications to the use of the Healon GV OVD when used as recommended.

#### Precautions

Precautions normally considered during ophthalmic surgical procedures should be taken.

Postoperative intraocular pressure may be increased if the Healon GV OVD is left in the eye. Due to the greater viscosity of the Healon GV OVD, this increase in postoperative IOP may be higher than that caused by leaving the same amount of other sodium hyaluronate viscoelastic products, with lower zero shear viscosity, in the anterior chamber. Since rises in postoperative intraocular pressure, including cases of significant elevation and subsequent complications, have been reported, the following precautions are strongly recommended:

- Special care should be taken to ensure as complete removal as possible by continuing to irrigate/aspirate after you see displacement of the initial bolus of viscoelastic from the eye, continued irrigation/aspiration should facilitate removal of viscoelastic which may remain in the anterior segment.
- Pre-existing glaucoma, other causes of compromised outflow, higher 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.
- Carefully monitor intraocular pressure, particularly during the early postoperative period.
- Treat with appropriate intraocular pressure lowering therapy, if required.

The Healon GV OVD is a highly purified fraction extracted from avian tissues which may contain minute amounts of protein. The potential risks associated with the injection of biological material should be considered.

Express a small amount of the Healon GV OVD from the syringe prior to use and carefully examine it during use to avoid injecting minute rubber particles which may be released when the syringe diaphragm is punctured.

Sodium hyaluronate solution may appear cloudy or form precipitates when it is injected. Based on *in vitro* laboratory studies, this phenomenon may be related to interactions with concomitantly used ophthalmic medications or detergents which remain in reused cannulas.

Reprocessed cannulas should not be used.



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