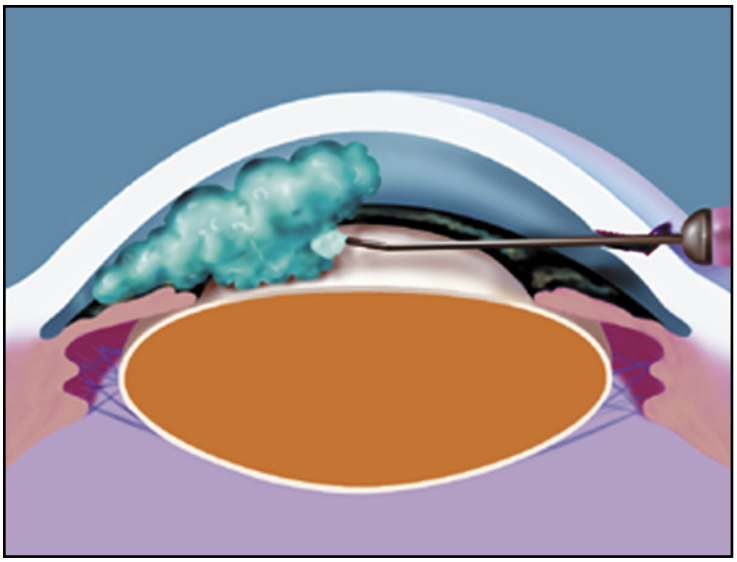
VISCO SHIELD®

OPHTHALMIC VISCOSURGICAL DEVICE

VISCO SHIELD® is a dispersive HPMC viscoelastic composed of a a sterile, high molecular weight, hydroxypropyl methylcellulose solution for use in anterior segment surgical procedures including cataract extraction and intraocular lens implantation.

The highly lubricous VISCO SHIELD® protects the corneal endothelial cells during ophthalmic surgical procedures and can be easily aspirated from the anterior chamber following surgery.

VISCO SHIELD® is optically clear and can be stored at room temperature.



FOR EXPORT ONLY

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Protects delicate eye tissues while maintaining the chamber.

- 8,000 cps or 20,000 cps
- HPMC molecular weight greater than 400,000 Daltons
- Osmolarity 200 – 400 milliOsmoles
- Stores at room temperature
- 2.0 ml fill size
- Packaged sterile with cannula
- 6 syringes per dispenser box

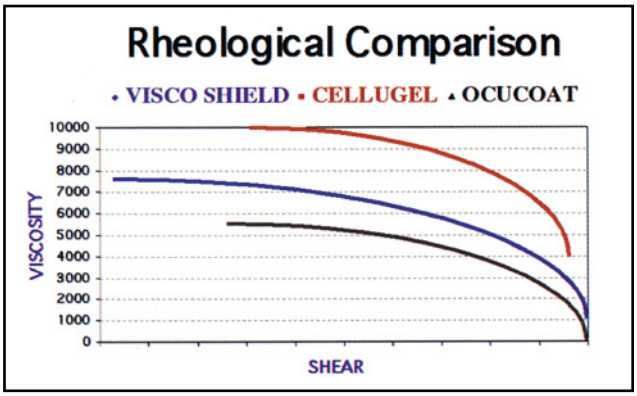

Chart:
VISCO SHIELD® Data on file at OASIS Medical.
Cellugel is a registered trademark of Alcon.
Occucoat is a registered trademark of Bausch & Lomb.

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OASIS®

PRODUCT INFORMATION

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DESCRIPTION

Each 1 ml of VISCO SHIELD® contains approximately 16 to 20 mg/ml of hydroxypropyl methylcellulose premium USP/EP dissolved in a physiologically compatible buffering solution containig 6.40 mg Sodium Chloride UPS, 0.75 mg Potassium Chloride USP, 0.48 mg Calcium Chloride Dihydrate USP, 0.30 mg Magnesium Chloride Hexahydrate USP, 1.70 mg Sodium Citrate Dihydrate USP and 3.90 mg Sodium Acetate Trihydrate in Water For Injection UPS. The pH is 6.8 to 7.6 and the osmolarity is 200 to 400 milliOsmoles.

CONTRAINDICATIONS

Presently, there are no known contraindications to the intraocular use of hydroxypropyl methylcellulose viscoelastic when used as recommended.

PRECAUTIONS

Precautions associated with the use of VISCO SHIELD® relate to the surgical procedure being performed. The following precautions are recommended:

1. Do not over fill the anterior chamber of the eye with VISCO SHIELD®. Overfilling may cause increased intraocular pressure, glaucoma or other associated ocular damage.
2. Remove as much as possible of the VISCO SHIELD® at the close of surgery by irrigation/aspiration. Use care to avoid injury to the corneal endothelial cells as a result of the removal procedure.
3. Monitor postoperative intraocular pressure. If significant rises occur, treat with appropriate therapy. Postoperative intraocular pressure should be evaluated as a result of pre-existing glaucoma, impeded outflow, and as a result of related operative procedures which may include enzymatic zonulyses, absence of an iridectomy, trauma to filtration structures, and by blood and lenticular remnants in the anterior chamber.
4. The concurrent presence of medication(s) in the anterior chamber of associated ocular structures may interact with VISCO SHIELD® to cause clouding.
5. VISCO SHIELD® is preservative free and should be discarded after a single use. Avoid using any excess viscolastic or reusing the delivery cannula. Do not resterilize.
6. VISCO SHIELD® should be used at ambient temperature. Protect from direct light and freezing and excessive heat

ADVERSE REACTIONS

Hydroxypropyl methylcellulose viscoelastic is tolerated well after injection into human eyes. A transient rise of intraocular pressure postoperatively has been reported. Isolated incidences of post-operative inflammatory reactions (iritis, hypopyon) as well as corneal edema and corneal decompensation have also been reported. Their relationship to hydroxypropyl methylcellulose viscoelastics has not been established.

CLINICAL APPLICATIONS

Remove the syringe of VISCO SHIELD® and the delivery cannula from the pouch. VISCO SHIELD® is guaranteed to be sterile unless the pouch is damaged or opened. Attach the cannula to the syringe and bleed the air from the cannula by ejecting a small amount of viscoelastic.

Slowly introduce a sufficient amount of VISCO SHIELD® into the anterior chamber to fill the eye. The injection of VISCO SHIELD® can be performed either before or after the removal of the crystalline lens. Injection of VISCO SHIELD® prior to lens removal will have the additional advantage of protecting the corneal endothelium from possible damage during the removal process. Additional volumes of VISCO SHIELD® can be injected during the procedure to replace any viscoelastic lost during surgery.

VISCO SHIELD® may also be used to coat surgical instruments and the intraocular lens prior to insertion and to lubricate instruments such as folded lens inserters.

Extensive pre-clinical and clinical testing has been performed on hydroxypropyl methylcellulose viscoelastics. This material has been shown to be safe and effective for use as an intraocular viscoelastic. VISCO SHIELD® HPMC viscoelastic has been tested and shown to be sterile, non-pyrogenic, non-cytoxicity, non-irritating in the Rabbit Anterior Chamber Irritation test, and free of potentially antigenic proteinaceous material.

STORE AT ROOM TEMPERATURE 15°–40°C (59°–104°F)
PROTECT FROM FREEZING AND LIGHT
DO NOT USE THIS PRODUCT AFTER THE EXPIRATION DATE

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

STERILE

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