

PRODUCT INFORMATION

VISCO SHIELD®

2% HPMC Viscoelastic

DESCRIPTION

Each 1ml of VISCO SHIELD contains approximately 20 mg/ml of hydroxypropyl methylcellulose premium USP/EP dissolved in a physiologically compatible buffering solution containing 6.40 mg Sodium Chloride USP, 0.75 mg Potassium Chloride USP, 0.48 mg Calcium Chloride Dihydrate USP, 1.70 mg Sodium Citrate Dihydrate USP and 3.90 mg Sodium Acetate Trihydrate in Water For Injection USP. 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 viscoelastic 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 greater than 40°C.

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 postoperative 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 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 2% HPMC viscoelastic has been tested and shown to be sterile, non-pyrogenic, non-cytotoxicity, non-irritating in the Rabbit Anterior Chamber Irritation test, and free of potentially antigenic proteinaceous material.

STORE AT ROOM TEMPERATURE 15°-30° (59°-86°F)
PROTECT FROM FREEZING AND LIGHT
DO NOT USE THIS PRODUCT AFTER THE EXPIRY DATE

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

STERILE

European Medical Device Representative:
Donawa Consulting Srl
Piazza Albania 10
00153 Rom, Italy

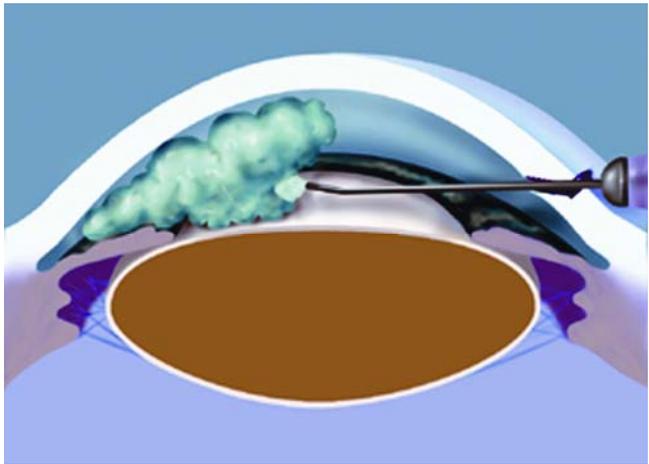


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VISCO SHIELD®

2% HPMC VISCOELASTIC



VISCO SHIELD® 2% HPMC viscoelastic is a sterile, high molecular weight, hydroxypropyl methylcellulose solution for use in anterior segment surgical procedures including cataract extraction and intraocular lens implantation.

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.

Protects delicate eye tissues while maintaining the chamber

- 8,000 and 20,000 cps HPMC
- stores at room temperature
- 2.0ml fill size
- packaged sterile with cannula
- 6 syringes per dispenser box

Rheological Comparison

◆ VISCO SHIELD ■ CELLUGEL ▲ OCUCOAT

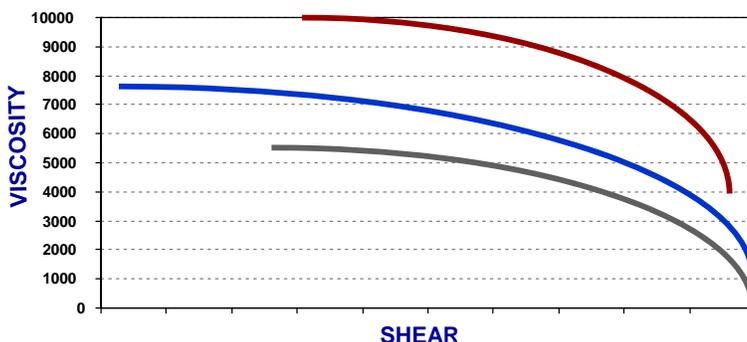


Chart: VISCO SHIELD Data on file at OASIS Medical
 Cellugel is a registered trademark of Alcon.
 Ocucoat is a registered trademark of Bausch & Lomb.



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