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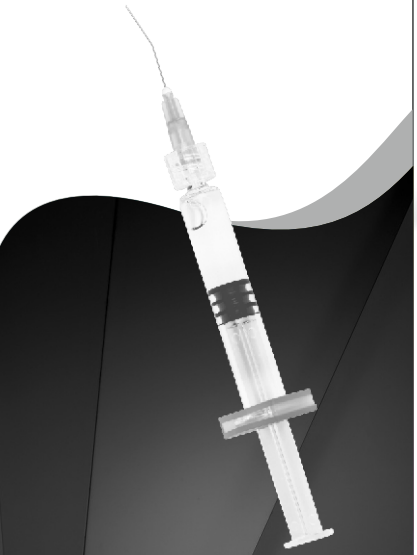
DEVINE
MEDITECH

Sodium Hyaluronate Ophthalmic Solution



Supplied in a sterile Pre-filled Syringe with grip and a sterile single use cannula.

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DM/IFU/OVD/04 Ver.01

- alter the viscosity of the solution
- compromise the clarity of the solution
- be the cause of cross contamination and for transmission of bacteria and viruses
- Do not re-sterilize the device. Resterilization of the OVD will have a detrimental effect on its rheological and chemical properties thereby rendering it inappropriate for the intended use.
- Ensure safe and proper disposal of used/discarded product and packaging as per established procedure for handling biomedical waste

STORAGE

- Store between 15° to 30°C
- Protect from light & freezing
- Expiry date showed on the pack indicates the period within which the device has to be used.

RETURN OF DAMAGED PRODUCT

Return the OVD in its original box identified by the LOT number, your purchase reference and reason for the return.

DISPOSAL OF DISCARDED PRODUCT AND PACKAGING

Ensure safe and proper disposal of used/discarded product and packaging to avoid adverse effect to environment, children and stray animals. The disposal should be in compliance to local laws related to disposal of biomedical waste, in the country of use.

DESCRIPTION

Devine Meditech Sodium Hyaluronate Ophthalmic solution is a Ophthalmic Viscosurgical Device (OVD) with its application as a surgical aid in the anterior segment during cataract extraction and intraocular lens (IOL) implantation. It is a sterile, isotonic, viscoelastic solution of highly purified, non inflammatory Sodium Hyaluronate with a high molecular weight. The Sodium Hyaluronate material is derived from bacterial fermentation. It is available in concentration of 14 mg and 18 mg.

This Viscoelastic Preparation serves to maintain a deep anterior chamber during anterior segment surgery allowing reduced trauma to the corneal endothelium and surrounding ocular tissues. The viscoelastic properties of Sodium Hyaluronate Ophthalmic solution preparation help to push back the vitreous face and prevent formation of a flat chamber postoperatively.

INTENDED USE

Sodium Hyaluronate Ophthalmic Solution is Intended for use as a surgical aid during ophthalmic surgeries

- It is introduced in the Anterior Segment during Cataract extraction with or without Intraocular Lens Implantation.
- It serves to create/maintain a deep anterior chamber, to maintain the shape & to facilitate manipulation of ocular tissues.
- Viscoelasticity of the solution helps to push back the vitreous face and prevent

formation of a postoperative flat chamber.

- During IOL implantation surgery the OVD is used to coat intraocular lens as well as tips of surgical Instruments, prior to Implantation.
- Injecting the solution prior to lens delivery provides additional protection to the corneal endothelium and other ocular tissues,particularly with regard to mechanical damage to these structures from surgical instruments and equipment.

CONTRAINDICATIONS

- At present, there are no known contraindications, when used by a trained Surgeon, as recommended.
- Care should be exercised for use in patients with hypersensitivity components of the solution.

CONCENTRATION AND PACKIN

The solution is prepared by dissolving Sodium Hyaluronate powder in aqueous, isotonic solution. The molecular weight of the material is Min 3.0x 106 dalton. The pH range of the solution is maintained at 6.8 — 7.6. The characteristics of the solution are

Properties	1%	1.4%	1.8%	2.4%
Sodium HyaluronatePer ml	10mg	14mg	18mg	24mg
Shear Viscosity at 250C (in cps)	50000-125000	80000-200000	150000-500000	175000-800000

The solution is supplied as sterile preparation aseptically filled in a prefillable syringe (OVD container).The solution volume in the syringe is 0.5-2 ml. The syringe is placed in a medical grade paper pouch/blister alongwith with prepacked 25G/27G Cannula used for injecting. The cannula itself is sterilized by Ethylene Oxide (EO) before packing inside the pouch with Prefilled syringe. .

STERILIZATION

The OVD is aseptically filled and packed in blister/pouches. The cannula supplied along with the OVD is sterilized by Ethylene Oxide (EO). When placed in a blister pack, the outer surface of the OVD Container may be sterilized by Ethylene Oxide (EO).

INSTRUCTIONS FOR USE

- The OVD is to be used by a qualified and trained ophthalmic surgeon only.
- It is supplied sterile in a dry, heat sealed package.
- First, check the date of expiry of sterilization on the box and make sure that the sterility of the device is still valid.
- To remove the OVD, carefully peel open outer pouch/blister and remove the OVD container in sterile environment.
- Attach the supplied cannula to the leur-lock of the syringe. Turn the cannulatightly in the lock so that no solution may leak while being instilled.
- Before starting the use of the OVD, push the plunger of the syringe till some OVD solution comes out of the tip of the cannula. Now the device is primed for use.
- To instill the solution inside the patient eye, introduce the cannula end inside the eye through the incision made for surgery.
- Instill the solution gradually at the required site, inside the eye.
- Retract the cannula end from inside the eye and set the syringe aside for next instillation.
- If the solution is to be used as a lubricant to coat the surface of instrumentsor lenses, instill the solution on the target device gradually without the cannula touching its surface.
- This Instillation may be done under microscope but away from the eye to be operated.
- Risk of implantation: Ensure complete removal of OVD after surgery. The use of machine assisted Irrigation/Aspiration is recommended for removal.
- Post operatively, verify the absence of OVD in the eye during follow up

WARNINGS

- The OVD is to be used by a qualified and trained ophthalmic surgeon only.
- The OVD is for intraocular use only.
- Do not use the package if the integrity of the sterile package is compromised,
- Do not use the solution if it appears to be cloudy, colored or has floating particles/crystals/sediments of any kind.
- Do not use the solution if there are many air bubbles entrapped in the solution as it may affect the visualization during surgery.
- The OVD is for single use only. Reuse of the device may