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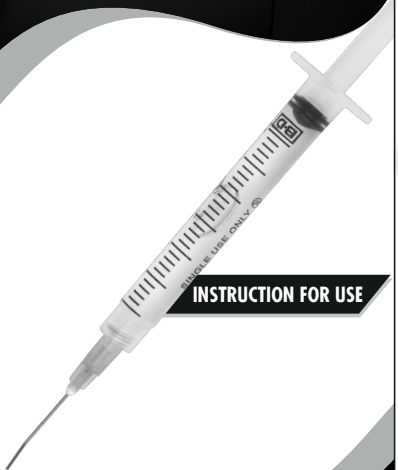
DEVINE MEDITECH

AkVisc PFS

Hydroxypropyl Methylcellulose Ophthalmic Solution



INSTRUCTION FOR USE

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

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additional OVD may be injected during anterior segment surgery to fully maintain the chamber, or to replace the fluid lost during the surgical procedure.

WARNINGS

- Do not use the package if the integrity of the sterile package is compromised.
- The OVD is for intraocular use only.
- The OVD is for single use only.
- The device is not to be placed in the direct sunlight or temperature exceeding 40°C
- Do not resterilize the device.
- Ensure safe and proper disposal of used/discarded product and packaging to avoid adverse effect to environment, children and stray animals.
- Expiry date showed on the pack indicates the period within which the OVD has to be used during surgery. The OVD should never be used after the expiry period

STORAGE

- Store at controlled room temperature and a relative humidity less than 65%. Protect from freezing.
- Do not expose containers to direct sunlight.
- During transportation, avoid temperatures above 50°Celsius and below 0° Celsius and use appropriate packaging protecting the OVD.

DESCRIPTION

Devine Meditech AkVisc: Hydroxy Propyl Methyl Cellulose (HPMC) solution is a sterile, isotonic, apyrogenic Ophthalmic Viscosurgical Device (OVD). It is a highly purified, non inflammatory solution useful for Anterior surgery composed of Hydroxypropyl methylcellulose (HPMC), an inert polymer that forms a viscoelastic solution in aqueous media. The solution is terminally sterilized by Steam

ACTIVE INGREDIENT

The main ingredient of the Viscoelastic solution is Hypromellose (HPMC). The solution has a high molecular weight greater than 80,000 daltons , viscosity of this solution is 4500 to 5500 cps and the pH is 6.0 to 7.8.

HOW SUPPLIED

The OVD is supplied as sterile, non-pyrogenic viscoelastic preparation supplied in a prefilled glass syringe of 2ml /3 ml or Glass vial of 5 ml. The OVD is aseptically filled in the container and is terminally sterilized by Steam Sterilization. The container is placed in a medical grade paper pouch/blister alongwith with prepacked 23G/22G Cannula used for injecting. The cannula itself is sterilized by Ethylene Oxide (EO) before packing inside the pouch with Prefilled syringe.

INDICATIONS

The OVD is indicated for use as an ophthalmic surgical aid in anterior segment surgical procedures, such as cataract extraction and intraocular lens implantation. The OVD maintains a deep chamber during anterior segment surgery and thereby allowing for more efficient manipulation with significantly less trauma to the corneal endothelium and other ocular tissues. The viscoelastic properties of the OVD helps the vitreous faced to be pushed back, thus preventing formation of a postoperative flat chamber.

It is intended for intraocular use only.

CONTRAINDICATIONS

At present, there are no known contraindications, when used by a trained Ophthalmic Surgeon, as indicated.

ACTIVE INGREDIENT

The main ingredient of the Viscoelastic solution is Hypromellose (HPMC). The solution has a high molecular weight greater than 80,000 daltons , viscosity of this solution is 4500 to 5500 cps and the pH is 6.0 to 7.8.

INSTRUCTIONS FOR USE

- The device is to be used by a qualified and trained ophthalmic surgeon only.
- The OVD is supplied sterile in medical grade paper pouch/blister.
- The package is terminally sterilized with steam sterilization/
- 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 container case in sterile environment.
- Carefully remove the OVD container. If the container is a pre-filled syringe, attach the supplied cannula to the leur-lock of the syringe. Turn the cannula in the lock so that the cannula may not come off while injecting the OVD.
- If the OVD container is a vial then aspirate or pour the contentsof the vial to a sterile syringe. And then affix a cannula to thesyringe as mentioned.
- The OVD must be fully removed at the end of the surgery. Rather thanaspirating the OVD from the eye with a syringe, it is recommended that the OVD be aspirated using an automated I/A device.
- OVD removed from the eye must be treated as clinical waste.

CLINICAL USE

In anterior segment surgery, OVD should be carefully introduced into the anterior chamber using a cannula. Injection of the OVD prior to lens delivery provides several clinical usages:

- Additional protection to the corneal endothelium and other ocular tissues, particularty with regard to mechanical damage to these structures from surgical instruments and equipment.
- It may also be used to coat an intraocular lens as well as tips of surgical instruments prior to implantation surgery.
- In case of foldable lenses, placing the OVD in the injector device prior to injecting the lens allows the lens to unfold readily without distortion and