MEDICONTUR E-IFU

MEDICONTUR VISCO-MC/ML/HL VISCOELASTIC SOLUTION FOR INTRAOCULAR USE INSTRUCTIONS FOR USE EN

MODEL

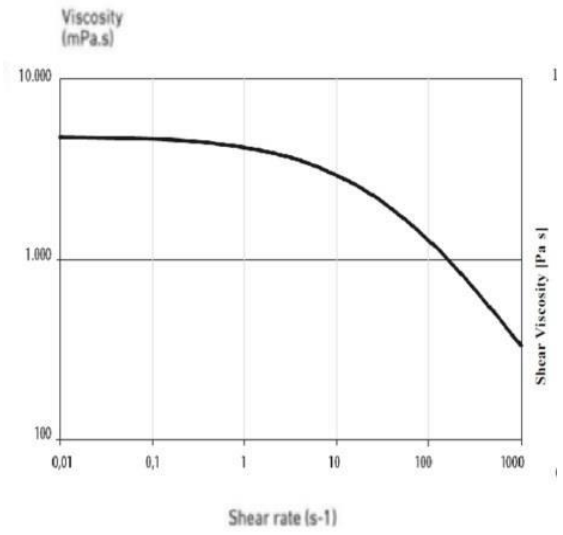
VISCO-MC viscoelastic solution for intraocular use 2.5 ml

DESCRIPTION

VISCO-MC: 2.5 ml highly dispersive, sterile, viscoelastic, clear, isotonic solution filled into a glass syringe with Luer lock, stopper, transparent plunger rod in blister (transparent plastic tray sealed with white foil). No materials of animal origin are used during manufacturing of the product or as raw materials. No pharmaceuticals are integrated into the product.

	Molecular weight (Daltons)	Osmolality (mOsmol/kg)	pH	Dynamic viscosity	Composition
VISCO-MC	approx. 516000	265-300	6.8-7.6	3200 mPa*s at a shear rate of 5 s-1 (Figure 1.)	20 mg/ml hydroxypropyl methylcellulose (HPMC), disodium hydrogenphosphate dodecahydrate, sodium dihydrogenphosphate dihydrate, sodium chloride and water for injection

Figure 1. Flowcurve of Visco-MC



PACKAGING

One syringe and one cannula in paper folding box.

VISCO-MC: One sterile 23 G single use cannula in separate primary packaging.

The OVD (Ophtalmic Viscosurgical Device) is sterilized by steam after being packed under clean room conditions. The cannula is sterilised by ethylene oxide. Sterility is guaranteed only when

the packaging is neither opened nor damaged.
The applied sterilisation procedure is marked on the folding box and the primary packaging.

STORAGE

VISCO-MC: 2-25°C.

Do not expose to direct sunlight.
Keep dry, protect from moisture/water.
Handle with care.

EXPIRATION DATE

Do not use this medical device after the expiry indicated on the carton/pouch/blister and the primary container.

INDICATION

Surgery of the anterior segment of the eye:

- to provide lubrication of the foldable intraocular lenses in the cartridge of the injectors,
- to maintain the depth of the anterior chamber during ophtalmic surgery in order to provide room for the efficient manipulation and to reduce the trauma of the corneal endothelium and the surrounding tissues.

PRECAUTIONS

- High level of surgical skill is required for proper use.
- Careful preoperative evaluation and clinical judgment should be made by the surgeon to decide the benefit/risk ratio of use.
- Special caution regarding the IOP (intraocular pressure) has to be exercised in patients suffering from pre- existing elevation of intraocular pressure and glaucoma.
- The volume to be applied depends on the type of the intervention.
- For the protection and lubrication of hydrophobic lenses within the injector system use a dispersive, HPMC based OVD.
- The IOP should be carefully monitored; in rare cases IOP-lowering therapy may be necessary, especially in patients with a compromised outflow facility.
- The IOP elevations may be caused by a reduction of aqueous outflow due to the blockage of the trabecular meshwork.
- The OVD must be removed completely by irrigation and/or aspiration at the end of an intervention. Check the position of the toric IOL after the removal of the OVD.

CONTRAINDICATION

Hypersensitivity to hydroxypropyl methylcellulose or any other components of the OVDs (see Composition).

COMPLICATIONS

As with any surgical procedure, there is risk involved. The risk can be reduced significantly with adherence to the instructions provided by the manufacturer.

The most common potential complications and undesirable effects accompanying the use of an OVD are closely related to the surgical intervention itself.
In the peri/postoperative period the use of OVDs may lead to

- transient increase of the intraocular pressure,
- distension of the capsular bag,
- anterior displacement of the intraocular lens or even capsular blockage - as reported in the literature.

Transient episodes of hypotension have been observed after phacoemulsification and intraocular lens implantation.
A case of severe anaphylaxis, probably caused by an equivalent HPMC product, was reported.

WARNINGS

- The product must only be used by ophthalmic surgeons.
- Use immediately after opening.
- Do not use if the sterilized package is open or damaged.
- Any occasional reuse must be avoided as it may pose serious health risk either by non-sterility or by any mechanical defect caused by the previous use.
- The cannula has to be fixed tightly on the Luer-lock cone of the syringe before use.
- The product has neither been tested in pregnant and/or breast-feeding women nor in children under 18 years of age.
- Keep the product out of sight and reach of children.
- Avoid injecting an excessive volume of the product into the eye.
- The product or its waste material should be disposed of in accordance with local/national regulations and requirements.

INTERACTIONS

No direct interactions with drugs are known. However, the OVDs may impair the efficacy of any therapy aiming the reduction of the IOP.

In reasonably foreseeable environmental conditions, no significant interaction or possible damage caused by exposition to magnetic fields, external electrical influences, electrostatic discharge, pressure or variation in pressure, thermal ignition sources, and acceleration is known.

PATIENT INFORMATION

The surgeon performing the intervention must inform the patient about the complete procedure and all known complications and risks.

The patient should be prepared to inform the doctor in charge properly about any adverse events experienced during/after procedure.

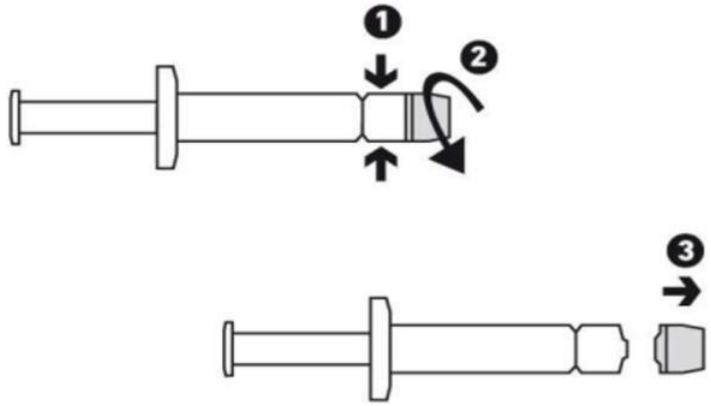
HANDLING

It is recommended to store the product at least one hour before administration at room temperature. Under strictly aseptic conditions open the blister/pouch at the marked end, take out the prefilled syringe.

DIRECTIONS FOR USE (Figure 4.-8.)

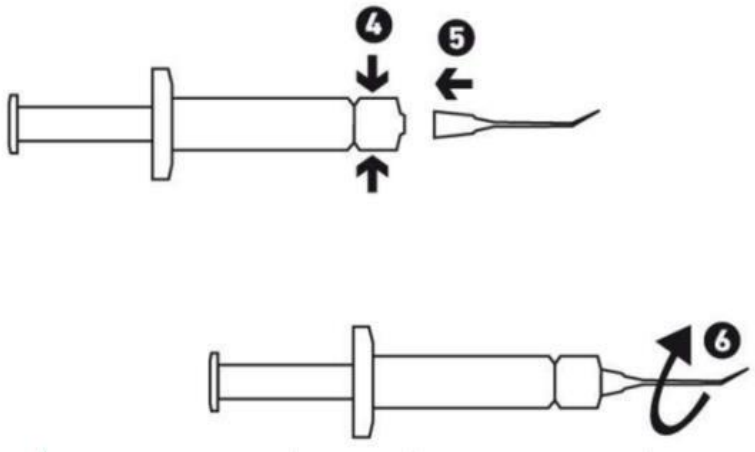
1. Hold the Luer-Lock adapter as shown in ❶ between your thumb and forefinger.
2. Twist the adapter carefully with the other hand in counter-clockwise direction ❷.
3. Remove the adapter gently as shown in ❸. This may prevent the formation of air bubbles.

Figure 4-5.



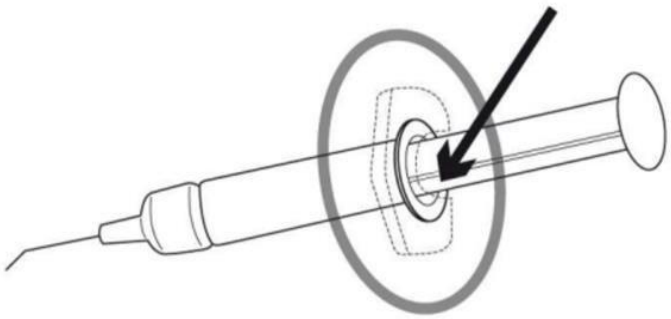
4. Hold the syringe as shown in ❹ between your thumb and forefinger.
5. Insert the enclosed cannula firmly ❺ (do not use any other cannula).
6. Hold the cannula and lock it into position by twisting lightly in a clockwise direction ❻.

Figure 6-7.



7. Hold the syringe during administration as shown in Figure 8. Open side of the backstop of the syringe should be positioned towards the palm.

Figure 8.



8. Use the product immediately after opening.

9. Apply the OVD through the cannula according to the local therapeutic protocol. Take into consideration the use of other medical devices and if necessary, read carefully their Instruction for Use.

10. After use, the cannula must be disposed to a sharps container.

LIABILITY

Medicontur does not bear any responsibility for improper model selection by the physician, for improper handling, use, surgical technique applied or for any other iatrogenic error caused by the implanting surgeon.

SYMBOLS - PACKAGING

CE 1639	CE certified		Keep dry		Do not re-use
	Keep away from sunlight		Consult instructions for use		Do not re-sterilize
LOT	Batch code		Use by date	STERILE	Sterilized using steam or dry heat
	Do not use if package is damaged		Manufacturer	STERILE EO	Sterilized using ethylene oxide
25°C 2°C	Temperature limit		Date of manufacture	SBS	Single sterile barrier system with protective packaging inside

MD	Medical device	UDI	Unique Device Identifier	⚠	Caution

MANUFACTURER

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Any adverse event that the lens may have caused, any serious incident should be reported to Medicontur's Quality Assurance at QA@medicontur.hu and to the competent regulatory authority.

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This document is executed in the English language. In the event of any inconsistencies, the English version shall prevail.