



## MEDICONTUR E-IFU

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Confidentiality Statement

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# MEDICONTUR VISCO-MC/ML/HL viscoelastic solution for intraocular use INSTRUCTIONS FOR USE EN

VISCO-MC viscoelastic solution for intraocular use 2.5 ml
VISCO-ML viscoelastic solution for intraocular use 1.5-1.6 ml
VISCO-HL viscoelastic solution for intraocular use 1.0-1.1/1.4 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.

VISCO-ML: 1.5-1.6 ml clear, sterile, viscoelastic solution filled into a glass syringe with clear plunger rod and Luer lock in pouch covered with transparent green foil.

VISCO-HL: 1.0-1.1 ml clear, sterile, viscoelastic solution filled into a glass syringe with purple plunger rod and Luer lock in pouch covered with transparent purple foil.

1.4 ml clear, sterile, viscoelastic solution filled into a glass syringe with red plunger rod and Luer lock in pouch covered with transparent green foil.

	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 <sup>-1</sup> (Figure 1.)	20 mg/ml hydroxypropyl methylcellulose (HPMC), disodium hydrogenphosphate dodecahydrate, sodium dihydrogenphosphate dihydrate, sodium chloride and water for injection
VISCO-ML	approx. 500000	200-400	6.8-7.6	20-40 KcPs (Figure 2.)	1.8-2.2 % HPMC, balanced salt solution (BSS)
VISCO-HL	approx. 1000000	200-400	6.8-7.6	20-60 KcPs (Figure 3.)	1.4-2.0 % sodium hyaluronate, balanced salt solution (BSS)

Figure 1. Flowcurve of Visco-MC

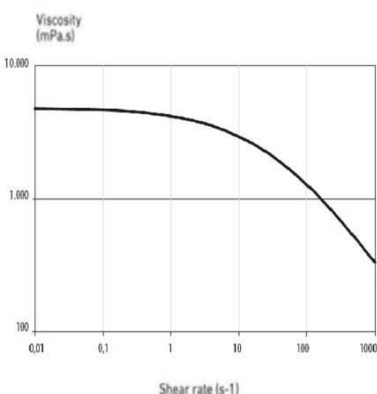


Figure 2. Flowcurve of Visco-ML

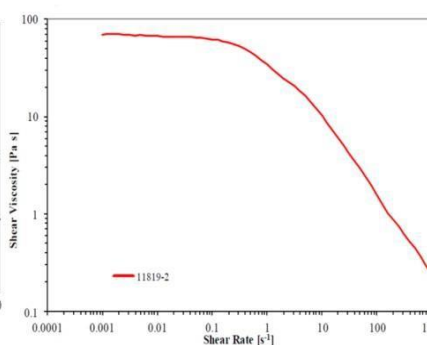
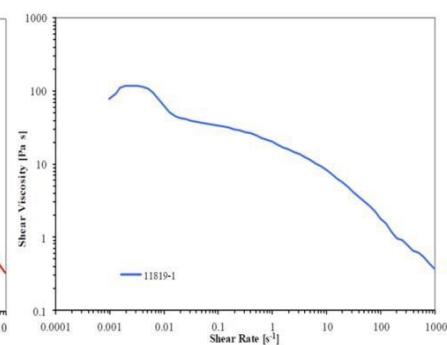


Figure 3. Flowcurve of Visco-HL



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**PACKAGING**

One syringe and one cannula in paper folding box.

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

VISCO-HL: One sterile 27 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.

VISCO-ML: Store between 10-30 °C.

VISCO-HL: Store between 10-30 °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 / sodium hyaluronate 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.

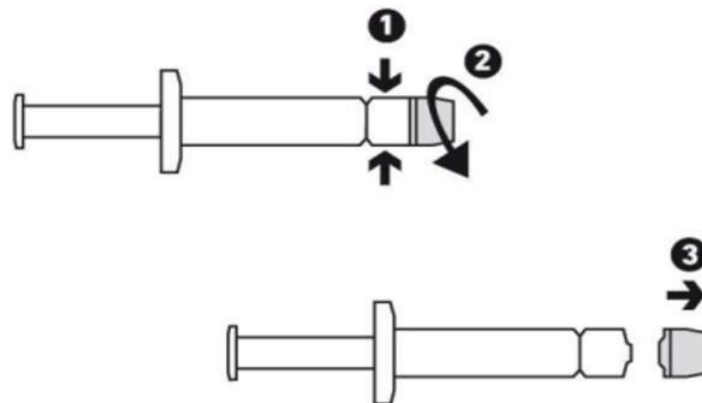
### **HANDLING**

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.)**

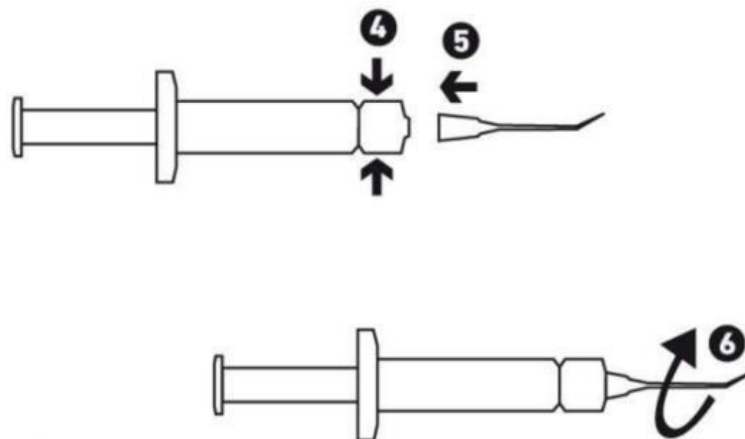
1. Hold the Luer-Lock adapter as shown in ① between your thumb and forefinger.
2. Twist the adapter carefully with the other hand in counter-clockwise direction ②.
3. Remove the adapter gently as shown in ③. This may prevent the formation of air bubbles.

Figure 4-5.



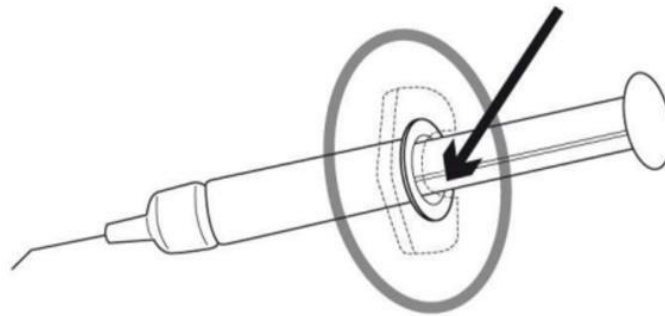
4. Hold the syringe as shown in ④ between your thumb and forefinger.
5. Insert the enclosed cannula firmly ⑤ (do not use any other cannula).
6. Hold the cannula and lock it into position by twisting lightly in a clockwise direction ⑥.

Figure 6-7.



7. Hold the syringe during administration as shown in Figure 8. In case of Visco-MC the 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**

<p>Do not re-sterilize</p>	<p>Do not re-use</p>	<p>Keep away from sunlight</p>
<p>Keep dry</p>	<p>Sterilized using steam (Product)</p>	<p>Consult Instructions for use</p>
<p>Use by date</p>	<p>Sterilized using ethylene oxide (Cannula)</p>	<p>Batch code</p>
<p>Do not use if package is damaged</p>	<p>Manufacturer</p>	<p>CE certified</p>
<p>Temperature limit</p>	<p>Temperature limit</p>	

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**LAST UPDATE**

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