

TEKNOMEK

EN

Medikal Malzemeler San. ve Tic. Ltd. Şti.

HYDROXYPROPYL METHYLULOSE (VISCOTEK) INSTRUCTIONS FOR USE
Read the instructions for use cautiously!

1.PRODUCT INFORMATION

Product Name: Hydroxypropyl Methylcellulose

Product Model: See the catalog or web-site for the models

BUDI-DI : 868054899026NM

Product Concentration Percentages: 2%, 2.4%

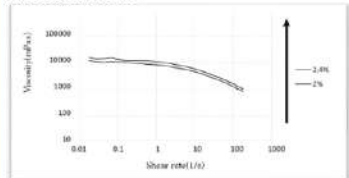
Size: 1 or 2 milliliters (in a glass syringe)

Shelf Life: Shelf life is two years. Stated on the product.

Class: IIb

Chemical Properties	Viscotek %2	Viscotek % 2.4
Methylcellulose Concentration Percentage	%2	%2.4
Molecular Weight	900,000-1,100,000 Da	900,000-1,100,000 Da
pH	6.9-7.6	6.9-7.6
Density	0.987-0.995 g/cm ³	0.992-0.998 g/cm ³
Concentration	20mg/ml	24mg/ml
Viscosity	10,000-20,000mPa.s	20,000-30,000mPa.s
Osmotolality	200-400mOsm/kg	200-400mOsm/kg
Endotoxigenicity	<0.2EU/ml	<0.2EU/ml
Refractive Index	1.337-1.338	1.337-1.338

Rheological Profile



Methylcellulose is a sterile, single use, surgically invasive viscoelastic solution. Methylcellulose is a clear, colorless, odorless and sterile solution for intraocular use. Does not contain any preservatives. It is indicated for use as an assistant material to ophthalmic surgery in any anterior segment procedures like cataract extraction and intraocular lens implantation. The solution contains hydroxypropyl methylcellulose in physiological saline solution at different concentrations.

2.PACKAGING and STERILIZATION

Methylcellulose is offered in 1 ml or 2 ml sterile single use glass syringes. The product is offered with a 23-27 G thin blind sterile single use cannula. The product is in ready-to-use form. The amount is specified on the product packaging. Products are sterilized by steam sterilization.

3.INTENDED PURPOSE

Corneal endothelial cells may be damaged, in case the space between the corneal endothelium and the anterior chamber is not maintained during surgery, causing corneal decompensation. Viscoelastic solution is injected to protect the corneal by protecting the cavity in the anterior chamber. The main objective of viscoelastic is to create a protective barrier for the corneal endothelium or to ensure intraocular lenses to slide out of their cartridges during operation. Methylcellulose protects chamber depth, endothelial layer, other intraocular tissues during anterior segment surgery and this allows more efficient manipulation with significantly less trauma to the corneal endothelium and other ocular tissues.

3.1.Clinical Benefit

- Supports intraocular manipulations by creating volume and protecting the endothelium.
- Enables surgeons to easily perform surgical maneuvers during operations.

4.INDICATIONS

Methylcellulose solution is an ophthalmic surgical instrument used in surgical interventions regarding the anterior segment like cataract and intraocular lens

implantation (IOL), routine cataract surgeries, intraocular lens implantation, corneal transplantation, and glaucoma surgeries.

4.1.Patient Information

The targeted patient group includes all age groups, all nationalities, and the whole population in need of ophthalmologic surgery without indicating any weight restrictions. The International Patient Identification Card is issued to the patient with instructions to keep the implant as a permanent record and to show it to any future ophthalmologist.

4.2.Patient Preparation

The product is used in eye surgery. The patient is prepared for the surgical procedure in line with the doctor's instructions. The product does not require any special preparation and training.

5.CONTRAINDICATIONS

The surgeon should use careful pre- and peri-operative evaluation and solid clinical judgment to decide the benefit/risk ratio before administering a methylcellulose injection to a patient with one or more of the following conditions. The evaluation of each individual case is at surgeon's discretion.

- In patients who are sensitive to any substance in the solution,
- In patients with very high intraocular pressure,
- Use for children pregnant or lactating women is under the initiative of the ophthalmic surgeon.

6.SIDE EFFECTS

Temporary high intraocular pressure abnormalities may occur following the surgery. The patient should be warned that he/she should consult his/her doctor if intraocular pressure increases. Even though there are no cases reported up to the present, it may interact with concomitant medications and cause condensation. In case such a case is observed, physicians should consider this potential. Risk analysis conducted by the manufacturer's risk management team specified that the remaining risk is as low as reasonably possible.

7.USAGE

These are the instruments used during ophthalmic surgery. Should not be left in the eye after the procedure is completed. The amount to be injected varies in each specific case and should be designated by the surgeon during the operation. Do not mix with any other substance before use.

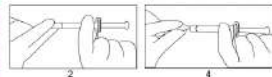
- Take out the products from the box.
- Open the product packaging just before use.
- Open the sterile packaged products taken out of the box to a sterile area by following the sterile opening rules and the opening direction shown on the package (Picture A)



Picture A: Symbol of Roll Pack Open Direction

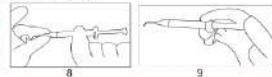
Instructions to remove the syringe luer cap correctly:

1. Take the syringe from the box out of its package.
2. Hold the syringe luer as shown.
3. Carefully twist the luer cap.
4. Remove the luer cap.



Instructions to place the cannula correctly:

5. Take the cannula from the box out of its package.
6. Hold the syringe.
7. Place the cannula on the syringe.
8. Twist and secure.
9. After the air is purged out of the cannula tip, the solution is ready to be injected. Methylcellulose viscoelastic is completely cleaned/removed from the eye by irrigation and/or aspiration method at the end of the surgery.



8.WARNINGS and PRECAUTIONS

⚠ It is for single-use.
⚠ Do not shake the product.
⚠ Do not re-sterilize. Reuse and/or resterilization may adversely affect device performance, which could seriously harm patient health and safety.
⚠ Do not use the product whose sterile package has been opened or damaged.
⚠ Apply with a sterile single use syringe and a sterile single use cannula.
⚠ Do not use expired products.
⚠ The product is restricted for use by surgeons trained in ophthalmic surgery.
⚠ Stop the application in case of an adverse reaction.
⚠ In case of any adverse reaction, notify the manufacturer.
⚠ Conduct the application according to the instructions written in the instructions for use. Otherwise the manufacturer is not responsible.
⚠ Use for children, pregnant or lactating women is under the initiative of the ophthalmic surgeon.
⚠ It should not be used in conjunction with other devices and/or general purpose equipment.
⚠ Suitable for intra-ocular use only.
⚠ Used for a short time in operations and must be completely cleaned following the operation.
⚠ Ensure that the product is completely cleaned following the application.
⚠ The remaining viscoelastic after surgical operation is naturally excreted through the trabecular system and Schlemm's canal. Intraocular pressure may increase in any case where the drainage channels may be blocked. In such a case, the surgeon should implement the appropriate treatment.
⚠ Even though there are no cases reported up to the present, it may interact with concomitant medications and cause condensation. In case such a case is observed, physicians should consider this potential.

9.WASTE DISPOSAL

Used products must be disposed of properly to avoid possible risks of infection. Disposal of the products after use should be performed by authorized persons in line with hospital procedures. Manufacturer is not responsible for waste disposal procedures.

10.STORAGE AND TRANSFER CONDITIONS

Store at temperatures between 10°C (50°F or 283.15°K) and 25°C (77°F or 298.15°K). Store in a dry place. Protect against light and impact. If it is wanted to be transferred, it can be transported in the boxes belonging to the product.

11.WARRANTY AND LIMITATION OF LIABILITY

Teknomek Medikal is not responsible for any injuries or damages that may arise from non-compliance with the recommendations and suggestions in the instructions for use and that are not suitable for the patient in the specified criteria. The risk of contamination which may arise from re-sterilizing the product by ignoring its single use quality is not the responsibility of the manufacturer. Teknomek Medikal is not responsible for the injuries or damages that the patient may suffer if it is not used by the doctor in line with the instructions for use.

12.SAFETY and CLINICAL PERFORMANCE

The product does not contain tissue, cell or derivatives of human or animal. There are no accessories and software for the device. There are no medicinal substances or biological materials included in the device as an integral part of the device. No CMR substances or materials that contain or consist of endocrine disruptors as an integral part of the device or that may cause sensitization or an allergic reaction to the patient or user are included in the device. Please contact the manufacturer for detailed safety and performance information.

13.RETURN and EXCHANGE POLICY

Please contact the manufacturer or your local distributor for the return or exchange of the product.

14.SYMBOLS

The symbols given on the product box and in the instructions for use are listed below.

🏭	Manufacturer
📦	Batch Code
🌡	Temperature Limit
💧	Humidity Limitation
🚫	Do not re-use
🔄	Do not re-sterilize.
📅	Use-by Date
⚠	Caution
☀	Keep away from sunlight
🧼	Sterilized using steam. Single sterile barrier system.
☔	Keep dry.
📖	Consult instructions for use.
🚫	Do not use if package is damaged and consult instructions for use.
🏠	Medical device
📄	Unique Device Identifier
🌿	Does not contain natural rubber latex.

15.ABBREVIATIONS

IFU	Instructions for Use
EN	English
%	Percentage
°K	Kelvin
°C	Centigrade
°F	Fahrenheit
CMR	Carcinogenic, mutagenic, reprotoxic substances
mPa	Mili pascal
Pa	Pascal
mPas	Mili pascal second
G	Gauge
ml	Milliliter
kg	Kilogram
mg	Milligram
g	Gram
g/ml	Gram/Milliliter
mg/ml	Milligram/Milliliter
EU/ml	Endotoxin per milliliter
mOsm/kg	Miliosmol / Kilogram
BUDI-DI	Basic Unique Device Identification - Device Identifier
Da	Dalton



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CE 2292 certified product



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Back: Explanation/Translation of Symbols

👤?	Patient name or patient ID number
🏠+	Name and address of the implanting healthcare institution / provider
📅	Implantation date
🏠	Device name
🏠	Name and address of the Manufacturer
📖	Information website for patients
📦	Lot number/ Batch Code
📄	Unique Device Identifier

En ophthalmic liquid



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International Implant Card



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