

TEKNOMEK

EN

Medikal Malzemeleri San. ve Tic. Ltd. Şti.

41 GAUGE SUBRETINAL INJECTION NEEDLE INSTRUCTIONS FOR USE
Read the instructions for use cautiously!

1.PRODUCT INFORMATION

Product Name: 41 Gauge Subretinal Injection Needle

Product Model: See the catalog or website for the models

BUDI-DI: 868054899001N5

Shelf Life: Shelf life is 3 (three) years. Stated on the product.

Class: IIa

It is a single use, sterile material used in ophthalmic surgical operations. The product contains a 41G polyimide tip passing through a stainless steel mounted on the handle. The tubing passing through the 41G subretinal injection needle is compatible for getting locked with the device and the injector tip.

2.PACKAGING and STERILIZATION

Products are sterilized by ethylene oxide sterilization. The product is offered sterile in double blister packaging. Product information is stated on the product packaging.

3.INTENDED PURPOSE

The product is used to administer liquid, air or medication under the retina

4.INDICATIONS

The product is used to administer or draw subretinal fluid in cases where macula detachment is required (subretinal-decalin, non-closing macular hole) in posterior segment surgery or to administer tPA in subretinal hemorrhages in the macula.

4.1.Patient Information

The targeted patient group includes all age groups, all nationalities, and the whole population when needed for vitrectomy surgeries without indicating any weight restrictions.

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

Should not be used by patients known to be allergic to any of the product ingredients. The evaluation of each individual case is at surgeon's discretion.

6.SIDE EFFECTS

Risk analysis conducted by the manufacturer's risk management team specified that the remaining risk is as low as reasonably possible.

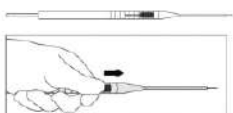
7.USAGE

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



Picture A: Symbol of Blister Pack Open Direction

- Push the pin on the handle forward to access the sub-retinal area



- Ensure that the 41-gauge needle comes out of the end of the metal tube.

7.1.Administering Fluid:

- 1.Lock the luer on the tubing end to the injector end.
- 2.The product is ready to use.

7.2.Drawing Liquid:

1. Lock the luer part of the tubing coming out of the product handle to the aspiration tubing of the device.
- 2.The product is ready to use.

8.WARNINGS and PRECAUTIONS

⚠	It is for single use.
⚠	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.
⚠	Do not use expired products.
⚠	The product is restricted for use by physicians specialized in surgery trained in ophthalmic surgery.
⚠	It must be considered that the tip of the product may be sharp, care should be taken while using.
⚠	Stop the application if any side effects occur. 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.

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 35 °C (95°F or 308.15°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 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. The products contain trace amounts of Nickel, which is one of the CMR substances. As a result of the risk management report conducted by the manufacturer's risk management team, the toxicological risks that the product may transfer to the patient in clinical use have been evaluated specific to contact time and the tissues where the contact is made, and it shows that the product is not cytotoxic, ocular irritant, skin sensitive and acute systemic toxic. In line with this result, the product is biocompatible. 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	Manufacturer
LOT	Batch Code
10°C - 35°C	Temperature Limit
20% - 70%	Humidity Limitation
⊘	Do not re-use.
⊘	Do not re-sterilize.
📅	Use-by Date
⚠	Caution
☀	Keep away from sunlight
STERILIZED	Sterilized using ethylene oxide. Single sterile barrier system containing protective packaging
☔	Keep dry.
📖	Consult instructions for use.
⊘	Do not use if package is damaged and consult instructions for use.
MD	Medical Device
UDI	Unique Device Identifier
🚫	Does not contain natural rubber latex.

15.ABBREVIATIONS

IFU	Instructions for Use
EN	English
%	Percentage
°K	Kelvin
°C	Centigrade
°F	Fahrenheit
G	Gauge
tPA	Tissue Plasminogen Activator
CMR	Carcinogenic, mutagenic, reprotoxic substances
BUDI-DI	Basic Unique Device Identification - Device Identifier

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Document No: IFU1.3
Rev.04/02.01.2023 (You can find the recent version and revision information on Teknomek's website.)

CE CE 2292 certified product
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