

TEKNOMEK

Medikal Malzemeleri San. ve Tic. Ltd. Şti.

MICROSURGICAL INSTRUMENTS, EQUIPMENT AND ACCESSORIES
INSTRUCTIONS FOR USE
Read the instructions for use cautiously!

1. PRODUCT INFORMATION

Product Name: Microsurgical Instruments, Equipment and Accessories

Product Model: See the catalog or website for models.

BUDI-DI: 868054899003N9

Size: Products are sized in line with types and lengths of their tip.

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

Class: IIa

Microsurgery is the open treatment of small structures of the human body that are usually indistinguishable with the bare eyes. Microsurgeries are performed with the implementation of high precision, high resolution microscopes and miniature surgical instruments, usually referred to as microsurgical instruments or equipment. Microsurgical instruments are used in many phases of ophthalmic operations such as holding or cutting tissue or particles. Included in the microsurgery equipment of Teknomek; lens chopper, nucleus chopper, Buratto's hook, micro manipulation tool, intraocular lens manipulation tool, forceps spatula, punctum dilator and probe, markers, flap lifter and manipulation tool, muscle hook, muscle vectis, scleral depressor and lid speculums are sterile, single use, surgically invasive medical devices. Products comprises of stainless steel and plastic handle.

2. PACKAGING and STERILIZATION

Products are sterilized by ethylene oxide sterilization. The product is packaged in rolls or with blisters. Product information is stated on the product packaging.

3. INTENDED PURPOSE

The intended purpose of microsurgery equipment included in Teknomek vary. Ophthalmic microsurgery and accessories are mainly used for sclera, iris, nucleus flip in eye surgeries, nucleus breaking in phaco surgery, and lens placement in the eye.

3.1. Foreign Body Forceps: Used for holding the foreign body while removing it from the eye.

3.2. Marker: It is used to mark the part of the eye that needs trocar or cutting.

3.3. Eye Speculum: Used for holding the eyelids open and retract the eyelid during surgery.

3.4. Spatula: Used for correcting the position during and after IOL placement.

3.5. Muscle Hook: Used for grabbing the eye muscles, stabilize tissue, or maneuver during strabismus surgery.

4. INDICATIONS

Indicated for ophthalmic surgeries, mainly operations such as anterior segment surgery, vitreo-retinal operations, iridectomy, capsulorhexis, lasik flap lift, strabismus, glaucoma.

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 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

It must be considered that the tip of the product may be sharp, care should be taken while using.

• 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 B)



Picture A: Blister Package

Opening Direction Symbol



Picture B: Roll Package

Opening Direction Symbol

The opened product is ready for use.

8. WARNINGS and PRECAUTIONS

⚠	It is for single use.
⚠	Do not re-sterilize. Reuse and/or re-sterilization 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. Do not use after the expiry date. 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
	Batch Code
	Temperature Limit
	Humidity Limitation
	Do not re-use.
	Do not re-sterilize
	Use-by Date
	Caution
	Keep away from sunlight
	Sterilized using ethylene oxide. 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
GIL	Intra-Ocular Lens
CMR	Carcinogenic, mutagenic, reprotoxic substances
BUDI-DI	Basic Unique Device Identification - Device Identifier



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CE 2292 certified product



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