

TEKNOMEK

Medikal Malzemeleri San. ve Tic. Ltd. Şti.

GENERAL INSTRUCTIONS FOR USE
Read the instructions for use cautiously!

1. PRODUCT INFORMATION

Product Name: Single use ophthalmic products, backflush handle, flexible set, tube set, ophthalmic set and textile, eye shield.

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

Shelf Life: Varies depending on the product types. Stated on the product.

2. PACKAGING and STERILIZATION

Products are sterilized by ethylene oxide sterilization. Product information is stated on the product packaging.

3. INTENDED PURPOSE

Includes the use of products as a set or single use ophthalmic products in ophthalmology surgeries.

4. INDICATIONS

Indicated for use in required ophthalmic surgeries.

4.1. Patient Information

The targeted patient group includes all age groups, all nationalities, and the whole population when needed for eye 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

Open the sterile packaging just before use. The products are 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.
⚠	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.
⚠	It must be considered that the tip of the product may be sharp, care should be taken while using.
⚠	Pay attention to the features of use as per the type of product you buy.

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 devices. 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 devices. 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 products.

14. SYMBOLS

The symbols given on the products' 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
°C	Centigrade
°K	Kelvin
°F	Fahrenheit
%	Percentage
CMR	Carcinogenic, mutagenic, reprotoxic substances
BUDI-DI	Basic Unique Device Identification - Device Identifier



Manufacturer: TEKNOMEK Medikal Malzemeleri Sanayi ve Ticaret Ltd. Şti Halıcıoğlu Mah. Okumuşoğlu Sok. No 2. K.5 34445 Beyoğlu, İstanbul, Türkiye
Tel: +90 212 369 1263, Fax: +90 212 210 3432
Website: www.teknomek.net
e-mail: info@teknomek.net
Document No: IFUG
Rev.07/02.01.2023 (You can find the recent version and revision information on Teknomek's website.)



CE 2292 certified product



Translated by:

Atlantik Tercüme Hizmetleri Tic. Ltd. Şti
Address: Kervançeşme Cad. Hark Sok. Çağdaş Apt. No:2/5 34381 Mecidiyeköy, İstanbul, Türkiye
Tel: +90 212 217 92 06
e-mail: info@atlantiktercume.com