

TEKNOMEK

Medikal Malzemeleri San. ve Tic. Ltd. Şti.

HIGH FLOW FILTER AND SYRINGE INSTRUCTIONS FOR USE
Read the instructions for use cautiously!

1. PRODUCT INFORMATION

Product Name: High Flow Filter and Syringe

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

BUDI-DI: 868054899028NR

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

Class: IIa

High-flow filter is a sterile, single use medical device that is typically used in combination with specific laboratory syringes to allow filtration of C3F8 and SF6 ophthalmic gases for biological molecule isolation (ultrafiltration), removal of particles, or the mobile phase of a chromatograph (microfiltration).

2. PACKAGING and STERILIZATION

Products are sterilized by ethylene oxide sterilization. The product is offered sterile. Product information is stated on the product packaging. High flow filter and syringe can be supplied separately upon request.

3. INTENDED PURPOSE

The high flow filter is used for microfiltration to sterilize the air before drawing. The air is drawn into the syringe after it is sterilized with a high-flow filter.

4. INDICATIONS

Indicated in surgical operations used to filter and prepare gas when gas tamponade will be used in vitrectomy operations.

4.1. Patient Information

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

Patients who had gas administration should avoid pressurized situations such as altitude, airplane travel, scuba or free diving, hyperbaric oxygen therapy. 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

The patient should be warned that she should consult his/her doctor in case of side effects. Stop the application in case of any side effects. Although it is a non-toxic gas, it can react with oxygen when inhaled. Inhalation should be avoided. In case of accidental inhalation of gas, go out for fresh air. Risk analysis conducted by the manufacturer's risk management team specified that the remaining risk is as low as reasonably possible.

7. USAGE

There are bold scale markings to assist with settings so that the C3F8 and SF6 gases can be dosed in a more precise way

• 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

• 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.
⚠	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.

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 303.15°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
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
☀	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
Latex	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



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CE 2292 certified product.



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