

1. PRODUCT INFORMATION

Product Name: Backflush Instruments

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 sterile, single use, hand-held, manual-operated medical device used to manipulate fluids during vitreoretinal surgery. The product comprises of metal or silicone (flat or brush type) tip, silicone tube and handle. It has a tube for aspiration and a wash bulb to wash the tissues stuck during aspiration.

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. Optionally, the backflush cannula and handle can be sold separately.

3. INTENDED PURPOSE

Backflush instruments are used for passive or active aspiration of intraocular fluids and residues during vitreoretinal surgery. Low and safe aspiration is performed using intraocular pressure (IOP) and flows through the ventilation hole in the backflow as a result of pressure difference. Occasionally, the hole is closed, and pressure is applied to the tubing by implementing the aspiration method (blood, dye, etc.) on the retina. There are two types which are active and passive, depending on the characteristics of connecting to the device. Pay attention to the features of use as per the type of product you buy. All sizes are represented by handle colors. (Table 1)

Table 1: Product Color Codes

PLASTIC		METAL	
GAUGE	COLOR	GAUGE	COLOR
20G	Yellow	20G	Yellow
23G	Dark Blue	23G	Blue
25G	Red	25G	Red
27G	Gray	27G	Gray

3.1. Active Backflush

The end of the active backflush reservoir is open, and the product grip is in connection with the tubing passing through it. This tubing is double-sided, and it is suitable for connecting to the device. Metallic and plastic types are available. The choice is left to the ophthalmic surgeon. All sizes are represented by handle colors.

3.2. Passive Backflush

One end of the passive backflush reservoir is closed, and the aspiration process is performed manually. It is not suitable to connect to the device. Metallic and plastic types are available. The choice is left to the ophthalmic surgeon. All sizes are represented by handle colors.

4. INDICATIONS

The product is indicated for use in the fluid removal control, internal drainage of subretinal fluid, retinal fold manipulation (proliferative vitreoretinopathy (PVR), giant tears, retinotomies, translocation) and simultaneous or sequential gas/liquid exchanges (liquid-air, air-gas, liquid-gas, liquid-PFC, PFC-gas).

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 operation in line with the doctor's instructions. The product does not require any special preparation and training.

5. CONTRAINDICATIONS

Care should be taken in terms of the danger it may cause during intraocular entry and exit since the aspiration power will be high at high liquid levels. 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 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 Blister Pack Open Direction

7.1. Active Backflush Usage:

The product is prepared for application by attaching it to the system suitable for the process to be performed.

7.2. Passive Backflush Usage:

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.
	Pay attention when using soft-tipped devices with valve inlet systems.
	To guarantee a stable intraocular pressure (IOP), check the pressure for compliance in the course of entry into the eye.
	In cases where we manipulate the eye while using the device, it may lead up to the metal finish to flex or bend since it is a small-scale device.
	In case unwanted tissue is stuck in the aspiration port, the aspiration must be cut and released before the device can be moved. After stopping the aspiration, traction and possible tearing of the tissue will be prevented.

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 or 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 containing protective packaging.
	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
G	Gauge
IOP	Intraocular pressure
CMR	Carcinogenic, mutagenic, reprotoxic substances
PVR	Proliferative vitreoretinopathy
PFC	Perfluorocarbon
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

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Translated by:

Atlantik Tercüme Hizmetleri Tic. Ltd. Şti

Address: Kervangemeç Cad. Hark Sok. Çağdaş Apt.

No:2/5 34381 Mecidiyeköy, İstanbul, Türkiye

Tel: +90 212 217 92 06

e-mail: info@atlantiktercume.com