

TEKNOMEK

Medikal Malzemeleri San. ve Tic. Ltd. Şti.

INTRAVITREAL INJECTION AND PHACO SET INSTRUCTIONS FOR USE
Read the instructions for use cautiously!

1. PRODUCT INFORMATION

Product Name: Intravitreal Injection and Phaco Set
Product Model: See the catalog or website for models.

BUDI-DI: Intravitreal Injection Set: 868054899017NL

Phaco Set: 868054899018NN

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

Class: IIa

Intravitreal Injection and Phaco Set products are ready-to-use, sterile, single use, surgically invasive, short-time use medical devices that contain the main components for injection and other surgical procedures in eye surgeries.

1.1. Intravitreal Injection Set Components:

The components of the set vary depending on the product model and the components are stated on the label on the package.

1.2. Phaco Set Components:

The components of the set vary depending on the product model and the components are stated on the label on the package.

2. PACKAGING and STERILIZATION

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

3. INTENDED PURPOSE

They are the sets of various ophthalmic surgical instruments and required materials intended to be used to perform an ophthalmic surgical procedure. Intravitreal injection and phaco set is used in vitreous injection and cataract surgeries. The intended use of the products in the set is given below.

3.1. Intended Use of Intravitreal Injection Set:

• **Cannula and Plastic Injector:** Used for drug administration during intravitreal injection.

• **Cotton Swabs:** It is used as a tamp to prevent vitreous leakage following the injection.

• **Glove:** It is the medical equipment that the surgery room personnel wear during the operation to prevent the contamination risk.

• **Table Cloth:** It is the cover laid on the table to maintain the sterility of the products during the surgery.

• **Drape:** It is used to prevent the liquids and similar fluids to flow during surgery.

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

• **Marker:** Used to mark the appropriate point of the eye for the trocar or injection.

• **Gauze Bandage:** Used during wiping by using batton for disinfection of eyes etc. tissues before surgery.

3.2. Intended Use of Phaco Set:

• **Pouched Drape:** With the help of the pouch on the drape, it allows the collection of liquids coming out of the eye after washing the eye.

• **Ophthalmic Knife:** Used to perform precise incisions in ophthalmic microsurgery operations.

• **Cannula and Plastic Injector:** Used for drug administration, aspiration, and irrigation in cataract surgeries.

4. INDICATIONS

Intravitreal injection and phaco sets are indicated for use in diabetic retinopathy, intravitreal injection surgery, retinal vascular diseases, and ocular inflammation.

4.1. Patient Information

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

• Open the product packaging just before use.
• Open the sterile packaged products 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



Picture B: Roll Package

Opening Direction Symbol Opening Direction Symbol

• The products are ready to use

8. WARNINGS and PRECAUTIONS

⚠	It is for single use.
⚠	Do not re-sterilize. Reuse and/or reesterilization 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.
⚠	The product contains natural latex, powder-free, single use gloves that may cause allergic and anaphylactic reactions.

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 reesterilizing 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. Any material that contains or consists 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 not included in 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 reesterilize.
	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
	Contains natural rubber latex.

15. ABBREVIATIONS

IFU	Instructions for Use
EN	English
%	Percentage
°K	Kelvin
°C	Centigrade
°F	Fahrenheit
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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