

TEKNOMEK

Medikal Malzemeleri San. ve Tic. Ltd. Şti.

SILICONE INJECTION AND EXTRACTION INSTRUCTIONS FOR USE
Read the instructions for use cautiously

1. PRODUCT INFORMATION

Product Name: Silicone Extraction and Injection Systems
Product Model: See the catalog or web-site for the models
BUDI-DI: 868054899022ND

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

Silicone Extraction and Injection Systems are sterile, single use, surgically invasive, temporary use medical devices used for injection and extraction systems. The product is used to inject and/or extract silicone oil, which is used as a tamponade in vitreoretinal surgery. The systems are connected to vitreoretinal devices. Luers on the tubes make the product compatible with electronic medical devices. There is contact with tissues, cells or body fluids.

2. PACKAGING AND STERILIZATION

Products are sterilized by ethylene oxide sterilization. The product is offered sterile in double sterilization rolls. Packaging validation is conducted based on packaging equipment and packaging materials, as per current standards. The instructions for use of the product have been prepared for three different systems produced to inject and/or extract the silicone oil from the eye. Systems vary according to their distribution in the package and Luer compatibility. Luer-device compatibility is given in the table below (Table 1: LUER COMPATIBILITY). Luers must be used with the compatible device.

Table 1: Luer Compatibility

A	Compatible with Bausch & Lomb
B	Compatible with Oertli
C	Compatible with Dorr & Alcon

The contents of the systems are given in the table below (Table 2: System Contents). Among the systems, the one that fulfills the need should be preferred and luer-device compatibility should be taken into consideration.

Table 2: System Contents

NO	SYSTEM	PACKAGING TYPES	LUER
1	Silicone Extraction Systems	Luer and silicone tubing, Ophthalmic cannulated injector and silicone tubing	Alcon, Oertli, Dorr
2	Silicone Injection Systems	Silicone tubing and 19G ophthalmic cannulated syringe, Silicone tubing and 20G ophthalmic cannulated syringe	Dorr
3	Silicone Extraction Systems	Silicone tubing and 20G ophthalmic cannulated syringe, Silicone tubing and 25G ophthalmic cannulated syringe, Silicone tubing and 25G ophthalmic cannulated syringe	Alcon, Oertli, Dorr

3. INTENDED PURPOSE

Used for the injection and/or extraction of silicone in vitreotomy surgery. It is used to remove and/or inject silicone oil in vitreoretinal surgeries such as retinal detachment, intravitreal hemorrhages and macular hole.

4. INDICATIONS

Used for injecting and/or extracting silicone oil, which is used as a tamponade in vitreoretinal surgery. Used in surgeries such as pars plana vitrectomy, macular holes, intravitreal hemorrhages, retinal detachment.

4.1. Patient Information:

The targeted patient group includes all age groups, all nationalities, and the whole population in need of ophthalmologic surgery without indicating any weight restrictions. The patient ID card or wristband is given to the patient with instructions to keep the implant as a permanent record and show it to any future ophthalmologist.

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

Surgeon should use careful pre- and peri-operative evaluation and solid clinical judgment to decide the benefit/risk ratio before injecting silicone oil to a patient with one or more of the following conditions. The evaluation of each individual case is at surgeon's discretion.

Should not be used;
• In patients known to be allergic to any of the product ingredients,
• In patients with known silicone allergy,
• In pseudophakic patients with a silicone intraocular lens (IOL).

• With non-sterile, open package silicone oil

6. SIDE EFFECTS

Use with non-sterile, opened silicone oil creates contamination risk. 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 Roll Pack Open Direction



- 1-Cannula
- 2-Syringe
- 3-Plunger Rod
- 4-Luer (compatible with syringe)
- 5-Luer
- 6-Luer (compatible with device)

Correct Instructions for Usage for Injecting Silicone Oil to the Eyes:

- 1-Lock the cannula to be used to inject silicone to the syringe tip. (Screw Part 1 in the figure into the Part 2)
- 2-If silicone oil is used in the vial, pour it into the syringe.
- 3-Push the plunger stopper mounted on the plunger rod tip in a way so there is no space between the plunger stopper and the silicone oil. (Insert Part 3 to Part 2)
- 4- Turn the plunger rod part of the third part and separate it from the piston at the end.
- 5- If there is any bubble left in the syringe, remove it from the cannula tip or the plunger stopper skirt by applying a little pressure from the side before attaching the tubing system.
- 6-Push the luer towards the end of the tubing into the back of the syringe containing the silicone oil. (Attach Part 4 to Part 2).
- 7-Place it in a way that the opening of the plastic lock reaches on the flap of the syringe. Twist the syringe half a turn to the right or left and lock the syringe. (Lock Part 5 to the junction of Part 2 and Part 4)
- 8-Attach the luer located at the end of the tubing to the air outlet of the device. (Attach Part 6 to the device).
- 9-Remove the lid on the cannula and make it ready for application.

Correct Instructions for Use for Extracting Silicone Oil:

- 1-Ensure that the cannula is locked at the tip of the syringe. (Attach Part 1 in Figure 2 to Part 2)
- 2-Insert the piston mounted on the plunger rod tip into the syringe, unscrew the plunger rod part from the plunger stopper. (Insert Part 3 into Part 2)
- 3- Turn the trigger part of the third part and separate it from the piston at the end.
- 4-Push the luer at the end of the tubing into the back of the syringe and attach it. (Attach Part 4 into Part 2).
- 5-Lock the luer at the end of the tubing to the air outlet of the device. (Attach Part 6 to the device).
- 6-Remove the lid of the cannula and make it ready for application.

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.
⚠	Dispose of waste in accordance with hospital procedures after use.
⚠	The risk of contamination arising from the reuse of the contents by ignoring the fact that the product is single use is not the responsibility of the manufacturer.
⚠	Extremely high-pressure settings can put the patient at risk.
⚠	Systems must be used with compatible luers.
⚠	The use of materials other than compatible products may affect system performance and create potential hazards.
⚠	Do not use if the packaging is open or damaged. Do not use the product after the expiry date. Do not use the product with wet packaging.
⚠	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.
⚠	Do not use the product whose sterile package has been opened or damaged.
⚠	Do not use expired products.
⚠	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 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. The systems are connected to vitreoretinal devices. Luers on the tubes make the product compatible with electronic medical devices. Essentially, they are used once in an operation. There is no contact with tissues, cells or body fluids. 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	
LOT	Batch Code
35°C	Temperature Limit
10°C	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
Sterilized	Sterilized using ethylene oxide. Double 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
Does not contain natural rubber latex	

15. ABBREVIATIONS

IFU	Instructions for Use
EN	English
°C	Centigrade
°K	Kelvin
°F	Fahrenheit
%	Percentage
IOL	Intra-Ocular Lens
G	Gauge
CMR	Carcinogenic, mutagenic, reprotoxic substances
BUDI-DI	Basic Unique Device Identification - Device Identifier

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