

TEKNOMEK

EN

Medikal Malzemeleri San. ve Tic. Ltd. Şti.

SILICONE OIL INSTRUCTIONS FOR USE
Read the instructions for use cautiously!

1. PRODUCT INFORMATION

Product Name: Silicone Oil
Product Model: See the catalog or web-site for the models
UDI-DI: 6603549902 IN6
Size: 10 ml (in glass vial or glass syringe)
Shelf Life: Shelf life is 2 (two) years. Stated on the product
Class: IIB

Technical	
Boiling Point:	>205°C
Melting Point:	<40°C
Specific Weight:	0.971
Smell:	Odorless
Water Solubility	Insoluble (<100ppb)

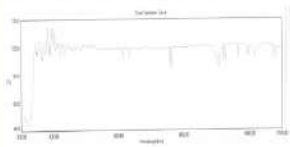
1.1 Chemical Properties

Silicone Oil	1000 cSt
Density	0.961 g/cm ³ - 0.970 g /cm ³
Viscosity	1000 cSt
Endotoxiciy	<0.2EU/ml
Refractive Index	1.403-1.404 at 25°C
Spectral Transmittance	Given graphically between 300 nm and 1100 nm.

Silicone Oil	1300 cSt
Density	0.961 g/cm ³ - 0.970 g /cm ³
Viscosity	1300 cSt
Endotoxiciy	<0.2EU/ml
Refractive Index	1.403-1.404 at 25°C
Spectral Transmittance	Presented graphically between 300 nm and 1100 nm.

Silicone Oil	5000 cSt
Density	0.965 g/cm ³ - 0.973 g /cm ³
Viscosity	5000 cSt
Endotoxiciy	<0.2EU/ml
Refractive Index	1.403-1.404 at 25°C
Spectral Transmittance	Presented graphically between 300 nm and 1100 nm.

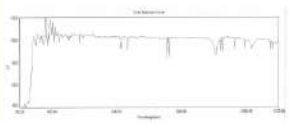
Spectral Transmittance Curve (1000 cSt)



Spectral Transmittance Curve (1300 cSt)



Spectral Transmittance Curve (5000 cSt)



Silicone oil is a transparent, odorless, colorless, sterile, single use, surgically invasive, ultraclean medical liquid. It is a purified, sterile vitreoretinal, fractionated apyrogen polydimethylsiloxane silicone oil for surgical purposes. This product does not contain phthalates and latex. Silicone oil is a very pure substance. Silicone oil is used as vitreous tamponade in vitrectomy surgery. For an easier application, silicone oil can be supplied with syringe, cannula, injection system.

2. PACKAGING AND STERILIZATION

Products are sterilized by steam sterilization. The products are offered in glass vial sealed with a polymer stopper and metal cap or in a syringe as a 10 ml. Depending on the disposable product code, the silicone injection cannula is

supplied with syringe and small glass vial form. The syringe form is ready to use. The amount and viscosity are stated on the product package.

3. INTENDED USE

Silicone oil is used as a substitute for the vitreous body in vitrectomy surgery. The product is preferred for a long-term ocular endotamponade in selected areas of complicated or uncomplicated recurrent retinal detachments.

3.1. Clinical Benefit

Helps in the surgical treatment of retinal detachment as a result of giant tear retinopathy, proliferative vitreoretinopathy, tractional diabetic retinopathy and traumatic retinopathy and other viral infections affecting the retina

4. INDICATIONS

It is a substance used as retinal tamponade (up to 29 days) postop with all RD (giant tear retinopathy, proliferative vitreoretinopathy, tractional diabetic retinopathy and traumatic retinopathy).

4.1. Patient Information

The targeted patient group includes all age groups, all nationalities, and the whole population requiring endotamponade following the vitrectomy surgery without specifying any weight restrictions. The international patient identification card is given to the patient with instructions to keep the implant as a permanent record and to show it to any ophthalmologist in future.

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 sound 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.

- 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).

6. SIDE EFFECTS

There are also risks in surgeries performed using silicone oil for the superior segment as with all surgical interventions. Usage below the required amount poses the risk of ineffective low tamponade. Redundant use may cause problems such as passing to anterior chamber and corneal problems, cataracts, and secondary glaucoma.

Ocular hypertonía, ocular hypotonia, choroidal detachment, corneal epithelial edema, cystoid macular edema, infection, endophthalmitis, glaucoma, keratopathy, transfer of silicone oil to the anterior chamber, and silicone intraocular lens opacification have been reported among the silicone-related side effects. Other side effects include optic nerve atrophy, rubeosis iridis, transient intraocular pressure increase, macular pucker, phthisis, and rupture, which are observed less. Passing of silicone oil into the anterior chamber may result in corneal changes including clouding, Descemet's folds, or corneal decompensation. If indisturbance is not performed at 6 o'clock position in aphakic eyes, pupillary block and angle closure may occur after silicone oil infusion. Risk analysis conducted by the manufacturer's risk management team specified that the remaining risk is as low as reasonably possible.

7. USAGE

The amount to be injected will vary in each specific case and must be determined by the surgeon during the operation. It must be checked whether there is a problem in the correct papillary circulation and feeding of the optic nerve during the infusion because it is impossible to determine the correct intraocular pressure in practice. In case suspected for such a situation, the infusion must be stopped immediately. Do not mix with any other substance before use.

- 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)
- Pay attention not to form air bubbles while drawing into the syringe from the glass vial.



Picture A: Roll Pack Open Direction

7.1. Correct Instructions for Use for Glass Vial:



1. Take the glass vial from the box out of its package.
2. Remove the cap of the glass vial.
3. Take the cannula from the box out of its package.
4. Hold the syringe.
5. Place the cannula on the syringe (which is suitable for delivery).
6. Twist and secure.
7. Perforate the polymer plug with the syringe. Pull the plunger rod to draw the product into the syringe.
8. Transfer the product from the vial to the syringe

7.2 Correct Instructions for Use for Glass Syringe



1. Take the syringe out of its package with its plunger rod.

2. Move the plunger rod to the appropriate space on the syringe.
3. Place the plunger rod by twisting it to the appropriate space and fix it.
4. Take the cannula from the box out of its package.
5. Hold the syringe luer as shown.
6. Carefully twist the syringe luer cap.
7. Remove the syringe luer cap.
8. Place the cannula on the syringe. Twist the cannula and secure. Product is ready to use.

8. WARNINGS AND PRECAUTIONS

⚠	It is for single-use.
⚠	Do not shake the product.
⚠	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.
⚠	Apply with a sterile single use syringe and a sterile single use cannula.
⚠	Suitable for intra-ocular use only.
⚠	Do not use expired products.
⚠	The product is restricted for use by surgeons trained in vitreoretinal surgery.
⚠	Stop the application if any side effects occur. In case of a previously unreported adverse reaction, notify the manufacturer.
⚠	Contact with the corneal endothelium is dangerous and precautions must be taken to avoid it. Furthermore, the passage of the substance under the retina must be prevented.
⚠	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 should be ensured that no other liquid remains in the vitreal cavity while applying the silicone oil.
⚠	The degree of intraocular lens may cause reactive errors when measured with standard formulas because the refractive index of silicone oil is high.
⚠	It is the surgeon's responsibility to select the patients, select the surgical procedure, and the length of time the silicone oil endotamponade in the eye (up to 29 days).
⚠	Intraocular lenses made of silicone can opacity with silicone oil. Therefore, silicone oil should not be applied to eyes with intraocular lenses (IOLs).
⚠	Visually inspect the substance to verify that it is clear and transparent before use. Do not use if it is blurry.
⚠	Glass injectors are potentially fragile and should be used carefully.

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. Waste disposal procedures are not under the responsibility of the manufacturer.

10. STORAGE AND TRANSFER CONDITIONS

Store at temperatures between 10°C (50°F or 283.15°K) and 25°C (77°F or 298.15°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

Use of the product is an operation involving ophthalmic surgery and has various risks regarding the eye surgery. Teknomex Medikal offered information and suggestions on such risks as well as the methods and techniques of the product. The doctor must share all the necessary information about this to the patients. Teknomex 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. Teknomex 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. The incidence of complications has been found to be lower

following the use of high-purity silicone oil, even though no coincidental relationship has been established with the purity of the silicone oil. Clinical experience has shown that silicone oil must be removed when the disease stabilizes or complications develop. 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	Manufacturer
LOT	Batch Code
15°C	Temperature Limit
Humidity Limitation	Humidity Limitation
Do not re-use.	Do not re-use.
Do not re-sterilize	Do not re-sterilize
Use-by Date	Use-by Date
Caution	Caution
Keep away from sunlight	Keep away from sunlight
Sterilized using steam. Single sterile barrier system.	Sterilized using steam. Single sterile barrier system.
Keep dry.	Keep dry.
Consult instructions for use.	Consult instructions for use.
Do not use if package is damaged and consult instructions for use.	Do not use if package is damaged and consult instructions for use.
Medical device	Medical device
UDI	Unique Device Identifier
Does not contain natural rubber latex.	Does not contain natural rubber latex.

15. ABBREVIATIONS

IFU	Instructions for Use
EN	English
%	Percentage
°K	Kelvin
°C	Centigrade
°F	Fahrenheit
ml	Milliliter
g	Gram
nm	Nanometer
g/ml	Gram/Milliliter
ppb	part per billion
IOL	Intra-Ocular Lens
CMR	Carcinogenic, mutagenic, reprotoxic substances
RD	Retinal Detachment
EU/ml	Endotoxin per milliliter
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: IFU10
Rev 07.02.01.2023 (You can find the recent version and revision information on Teknomex's website.)



2292 CE 2292 certified product

Translated by:

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

Back: Explanation/Translation of Symbols

En ophthalmic liquid

TEKNOMEK Medikal Malzemeleri Sanayi ve Ticaret Ltd. Şti

International Implant Card



TEKNOMEK MEDİKAL MALZEMELERİ
SANAYİ VE TİCARET İTİD. ŞTİ.

www.teknomek.net