594 mm

49,5 mm

200 mm

EN

TEKNOMEK

Medikal Malzemeleri San. ve Tic. Ltd. Şti.

OPHTHALMIC GASES INSTRUCTIONS FOR USE
Read the instructions for use cautiously!

1.PRODUCT INFORMATION

Product Name: Ophthalmic Gases (Oktafloropropan-C_3F_8 , Sulphurhexafluoride - SF_6)
Product Model: See the catalog or website for models.
BUDI-DI: For Octafluoropropane (C_3F_8): 868054899020N9 For Sulphurhexafluoride (SF_6): 868054899019NQ
Size :10 ml, 30 ml or 50 ml
Shelf Life: Shelf life is 3 years. Stated on the product.
Class:IIb

C_3F_8 Technical Features	
Name of the Gas:	Octafluoropropa
CAS Number:	76-19-7
Molecule Formula:	C_3F_8
Melting Point:	-183˚C (-297.4˚F)
Boiling Point:	-36.7˚C (-34.1˚F)
Molecular Mass:	188.03 g/mol
Appearance:	Colorless
Smell:	Odorless
Purity:	≥99.99
Steam Density:	6.69 (Air=1)
Gas Density: (lb/ft3)	0.4996
Vapor Pressure:	100.1 (psig)

SF_6 Technical Features	
Name of the Gas:	Sulfurhexafluoride
CAS Number:	2551-62-4
Molecule Formula:	SF_6
Melting Point:	-50.8˚C (-59.4˚F)
Boiling Point:	NA
Molecular Mass:	146.06 g/mol
Appearance:	Colorless
Smell:	Odorless
Purity:	≥99.99
Steam Density:	5 (Air=1)
Gas Density: (lb/ft3)	0.3847
Vapor Pressure:	320 (psig)

Technogases are non-toxic, inert, non-flammable, pure, colorless, and odorless. Technogases are used as a substitute for the vitreous substance following the vitrectomy. The product is available in sterile, custom produced pressurized aerosol boxes with high flow filter and cannula. The high flow filter is a sterile, single use, indirectly invasive, short-time (not contacting the body) medical device.

2.PACKAGING and STERILIZATION

Gas is non-sterile. The aerosol cylinder, cannula, filter, and syringe were sterilized with ethylene oxide. Microfiltration technique can filter bacteria from gas and/or air mixture by aseptic mechanism. By means of the microfiltration technique used, the gas is inserted into the syringe by being passed through microfilter as sterilized. The gases are ready to be administered intraocularly after microfiltration of ophthalmic intraocular gases. With non-sterile Octafluoropropane (C_3F_8) and Sulfurhexafluoride (SF_6) presented in an aerosol bottle the package contains a 50 ml plastic syringe for injection in vitreoretinal surgeries, 0.22-micron high flow filter, 30 Gauge needle, 1 (one) patient wristband and 1 (one) international implant card. The products are in aerosol form. Product amount is stated on the product packaging.

3.INTENDED PURPOSE

Technogas product groups (C_3F_8 and SF_6) are used as vitreoretinal tamponade in vitreoretinal surgeries. Gases provide the highest surface tension in comparison to other ingredients. A pure SF_6 balloon expands approximately 2 times in 24 to 48 hours and lasts for 1 to 2 weeks. A pure C_3F_8 balloon expands approximately 4 times in 72 to 96 hours and lasts for 6 to 8 weeks. The intraocular gas bubble has buoyancy that holds the retina against the retinal pigment epithelium since the specific gravity of any gas is lower than that of water. After the gas is injected, it expands in the eye, fills the vitreus cavity and displays a mechanical pressure effect.

3.1.Clinical Benefit

- •The intraocular gas bubble has buoyancy that holds the retina against the retinal pigment epithelium since the specific gravity of any gas is lower than that of water. Therefore, gases provide the highest surface tension in comparison to other ingredients.
- •Since the gas expands in the eye after it is injected, it has a mechanical effect.

4.INDICATIONS

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

- •As intraocular tamponade after PPV (retinal detachment, proliferative diabetic etiology, macular hole),
- •used to close the tear in Pneumatic retinopexy
- •In pneumatic displacement processes
- •Indicated for use as a replacement and intravitreal tamponade in subretinal hemorrhages.

4.1.Patient Information

The targeted patient group includes all age groups, all nationalities, and the whole population without any weight restriction, who have an indication for vitrectomy surgery and require postoperative tamp. 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. The international patient implant card and wristband are available in the box to be given to the patient for this product group.

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. If the patient is under general anesthesia, it is obligatory to discontinue the nitrogen protoxide anesthesia at least 15 (fifteen) minutes before starting the gas injection into the patient's eye. Ensure that as much of the central and peripheral vitreous is removed as possible before injecting the gas. In cases where gas is given as tamponade into the eye, the patient may need to be placed in a post-operative head position when necessary (e.g., macular hole). In such cases, it should be asked previously whether the head position shall be applied to the patient. Any specific training for the product is not required.

5.CONTRAINDICATIONS

The surgeon should use careful pre- and peri-operative evaluation and solid clinical judgment to decide the benefit/risk ratio before injecting C_3F_8 or SF_6 in a patient with one or more of the following conditions. The evaluation of each individual case is at surgeon's discretion.

- • Hypertonia,
- • Hypotonia,
- Glaucoma (narrow angle glaucoma)
- • Keratopathy,
- •Cataract,
- • Should not be used by patients with known intraocular inflammation and patients known to be allergic to any of the product ingredients.

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. During gas injection, monitoring of correct optic nerve head perfusion and possible optic nerve compression is essential, in which case the gas infusion should be discontinued immediately. Eye pressure should be monitored as a precaution to increase the intraocular pressure following the application. Regular follow-up frequency should be increased in glaucoma patients. Gas administered patients should definitely avoid nitrous oxide anesthesia. The risk of iatrogenic cataract formation should be considered. Potential side effects in the literature associated with in vitro retinal surgery: subretinal passage, haemorrhage, hematoma, choroidal tear, subconjunctival passage, passing to anterior chamber (aphakic patients), crystal lens or retinal contact during injection with the needle, refraction change, anterior chamber shallowing, inadequate position of gas bubble, retinal or vitreous incarceration at injection site, intraocular lenses especially condensation on silicone lenses. It is suggested that the patient wear the wristband included in the package to remind these side effects and warnings. Risk analysis performed by the manufacturer's risk management team determined that residual risk is as low as reasonably possible.

7.USAGE

It should be ensured that the vitreous is taken in sufficient amount, especially in aphakic eyes, due to the space-occupying nature of the gas, while it is left as tamponade after vitrectomy. It should be checked during the infusion whether there is a problem with the optic nerve head circulation and feeding the optic nerve since the exact determination of intraocular pressure is not possible in practice. In case suspected of such a situation, the infusion must be stopped immediately. If the eye is closed, ensure that there is a way out to avoid possible dangerous eye pressure while administering the product. Avoid pure gas injection in case of narrow irido-corneal angle; monitoring of the central retinal artery is required before and after gas injection. In case an expanding gas is used, monitoring of intraocular pressure is recommended during the gas expansion period. A follow-up protocol should be established after measuring and daily intraocular pressure should be monitored following the implantation.

The amount to be injected varies in each case and should be designated by the surgeon during the operation. They are not metabolized after implantation and are gradually eliminated through the bloodstream and respiration.

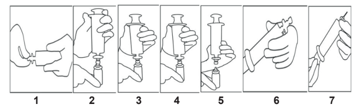
- •Take out the products from the box.
- •Open the product packaging just before use.

Gas is non-sterile. The product becomes aseptically sterile by passing through the supplied filter. The aerosol bottle is sterile.

- •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.

7.1. Correct Instructions for Use:



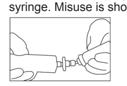
1.Check that the adapter is firmly connected to the syringe. Check whether the mechanism works correctly by pulling the trigger back and forth **(Picture 1).**
2.Hold the aerosol cylinder firmly. Push the connector of the filter halfway into the aerosol cylinder adapter without sliding it vertically to the right or left carefully and in a controlled manner **(Picture 2).**
3.Press precipitously against the syringe to transfer the gas to the syringe. Draw the amount of gas specified in column A into the syringe for each gas in Table 1 below. For each gas, fill the amount of air specified in column B of the table below to 50 ml by drawing into the syringe in order to obtain 50 ml of gas-air mixture for application by pulling back the syringe trigger **(Picture 3).**
4.Set the desired volume after drawing the gas into the syringe **(Picture 4).** Remove the aerosol from the syringe **(Picture 5).** Remove the filter **(Picture 6).** Fit on the cannula to the syringe tip immediately **(Picture 7)** and inject the gas-air mixture.

Table 1: Gas Quantity Determination

Gas name (SF_6 -C_3F_8)	Non-expanding Concentration (%)	A Pure gas	B Air volume
SF_6	20	10ml	40ml
C_3F_8	12	6ml	44ml

MIS-USAGE

Press precipitously against the syringe to transfer the gas to the syringe. Misuse is shown in the figure below **(Picture 8).**



8.WARNINGS AND PRECAUTIONS

⚠	It is for single use.
⚠	Use of pure gas is under the responsibility of the surgeon, be careful
⚠	Do not re-sterilize. Reuse and/or resterilization may adversely affect device performance, which could seriously harm patient health and safety.
⚠	Apply with a sterile, single use syringe, filter and cannula.
⚠	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 surgeons trained in vitreoretinal surgery.
⚠	Stop the application if any side effects occur. In case of any adverse reaction, notify the manufacturer.
⚠	Never remove the filter from the syringe while drawing gas and mixing with air. Apply by considering the items under the heading, usage. The manufacturer is not responsible for misuse.
⚠	Nitrogen protoxide anesthesia must be discontinued at least 15 (fifteen) minutes before initiating the gas injection into the patient's eye.
⚠	Ensure that as much of the central and peripheral vitreous is removed as possible before injecting the gas.
⚠	Proper papillary perfusion and possible optic nerve compression must be monitored during gas injection, in such a case the gas should be discontinued immediately.
⚠	Although non-toxic, the gases may react with oxygen when inhaled. Inhalation should be avoided.
⚠	In case of accidental inhalation of gas, go out for fresh air.
⚠	Eye pressure should be monitored as a precaution to increase the intraocular pressure following the application. Patients with glaucoma should be followed up regularly.
⚠	In case pulsation is observed in the central retinal artery during the application, paracentesis can be applied in the anterior chamber to balance the intraocular pressure.
⚠	Gases stipple the retina until they leave the eye after being injected into the eye. As time goes on, they come out of the eye by diffusion. After the diffusion of gases, the gas bubble is replaced by body fluid. Removal of the gas is spontaneous, requiring no secondary operation.
⚠	Patients who had gas administration should avoid pressurized situations such as altitude, airplane travel, scuba or free diving, hyperbaric oxygen therapy.
⚠	The patient should be informed that he/she should wear a wristband for the appropriate period of time and that he/she should not leave the international implant card with him/her.
⚠	It should not be used in conjunction with other devices and/or general-purpose equipment.
⚠	It must be considered that the tip of the product may be sharp, care should be taken while using.
⚠	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 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 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
LOT	Batch Code
10˚C 35˚C	Temperature Limit
20% % 70%	Humidity Limitation
②	Do not re-use
STERILIZE	Do not resterilize
⌛	Use-by Date
⚠	Caution
☀	Keep away from sunlight
STERILE EO	Sterilized using ethylene oxide. Single sterile barrier system.
☂	Keep dry.
i	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
%	Percentage
˚K	Kelvin
˚C	Centigrade
˚F	Fahrenheit
ml	Milliliter
g	Gram
G	Gauge
PPV	Pars Plana Vitrectomy
CMR	Carcinogenic, mutagenic, reprotoxic substances
CAS	Chemical Abstracts Service
RRD	Rhegmatogenous Retinal Detachment
BUDI-DI	Basic Unique Device Identification - Device Identifier
psig	Pounds per square inch
g/mol	Gram/mol

Manufacturer: TEKNOMEK Medikal Malzemeleri Sanayi ve Ticaret Ltd. Şti Karamehmet Mah. Avrupa Serbest Bölgesi 9. Sk. No:14 Ergene / Tekirdağ / Türkiye
Tel: +90 212 369 1263, Fax: +90 212 210 3432
Website: www.teknomek.net
e-mail: info@teknomek.net Document No: IFU9
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Translated by:
Atlantik Tercüme Hizmetleri Tic. Ltd. Şti
Address: Kervangeçmez Cad. Hark Sok. Çağdaş Apt.
No:2/5 34381 Mecidiyeköy, İstanbul, Türkiye
Tel: +90 212 217 92 06
e-mail: info@atlantiktercume.com