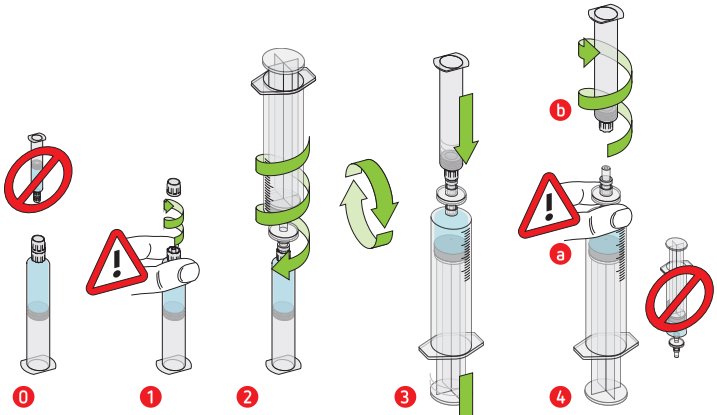
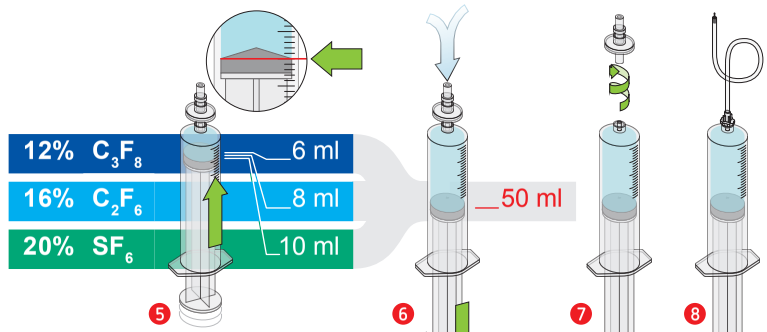
ophtha futur®

sf6
c2f6
c3f8

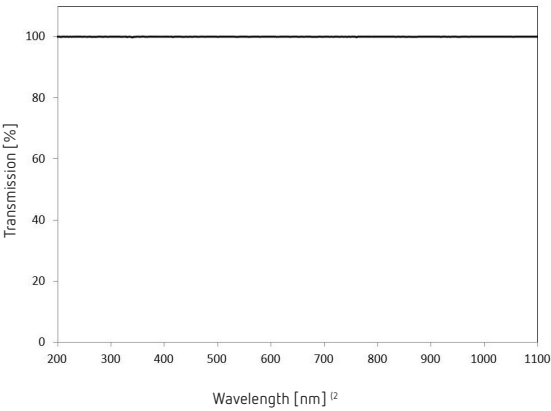
Nonverbal instruction |
Grafische Anleitung |
Instructions non verbales |
Instrucciones no verbales |
Istruzione non verbale |
Non-verbale instructies |
Neverbální instrukce |
Nonverbális utasítása |
Niewerbalne wskazówki |
невербальной инструкции |
Instrução não-verbal |
Σχηματικές οδηγίες |
Instrucţiuni nonverbale |
Icke-verbal bruksanvisning


0
1
2
3
b
a
4

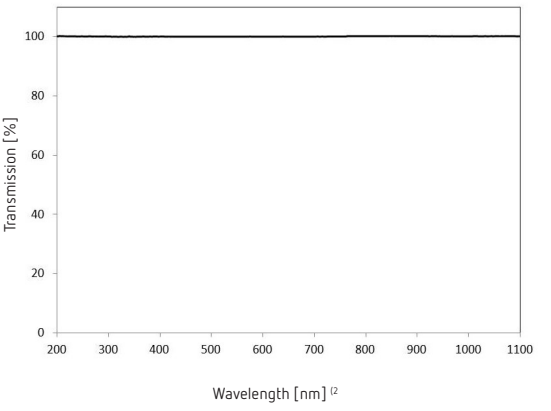

12% C_3F_8
16% C_2F_6
20% SF_6
6 ml
8 ml
10 ml
5
50 ml
6
7
8

Jazyky:
→ EN, DE, FR, ES, IT, NL, CS, HU, PL, RU, PT, EL, RO, SV

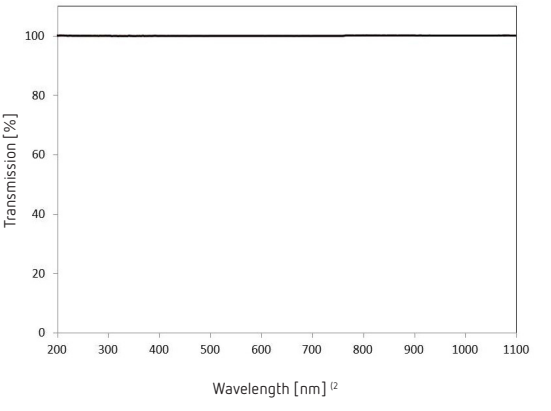
Křivka spektrální propustnosti [1] **ophthafutur® sf6**



Křivka spektrální propustnosti [1] **ophthafutur® c2f6**



Křivka spektrální propustnosti [1] **ophthafutur® c3f8**



(1 Curve of Spectral Transmittance | Spektrale Transmissionskurve | Courbe de Transmittance Spectrale | Curva de Transmisión Espectral | Curva di Trasmittanza Spettrale | Curve van de Spectrale Doorlaatbaarheid | Křivka Spektrální Propustnosti | Spektrális Áteresztési Görbe | KrzywaTransmitancji Widmowej | Кривая Спектрального Коэффициента Пропускания | Curva de transmissão espectral | Καμπύλη φασματικής διαπερατότητας | Curba de transmisie spectrală| Kurva för spektraltransmittans

(2 Wavelength | Wellenlänge | Longueur d'onde | Longitud de Onda | Lunghezza d'onda | Golflengte | Vlnová Délka | Hullámhossz | Długość Fali | Длина Волны (нм) | Comprimento de onda | Μήκος κύματος | Lungimea de undă| Våglängder

Information as of: | Stand der Information: | Informations en date de : | Información de: | Informazioni valide al: | Informatie per: | Informace ke dni: | A tájékoztató összeállításának időpontja: | atualizado das informações: | Informacja począwszy od: | Информация по состоянию на: | Ημερομηνία σύνταξης των πληροφοριών: | Informații din data de: | Information från den:

04/2024

Caution
This device may only be used in accordance with these instructions for use

Caution
Only qualified personnel may use the ocular endotamponades

Caution
Only for the intended use! Improper use of the ocular endotamponades can cause damage.

Outer surface sterilized with moist heat.

Do not use the product if the packaging is opened or damaged or if you have doubts about the sterility of the product.

Disposable product. Not suitable for reuse. The following risks can arise from unauthorized reuse: Infection due to insufficient sterility and/or biological contamination. Reuse can lead to invisible damage to the device and thus to insufficient functionality.

Reprocessing and re-sterilisation are not permitted. The following risks can arise from unauthorized reprocessing and re-sterilisation: Infection due to insufficient sterility and/or biological contamination. Reprocessing can lead to invisible damage to the device and thus to insufficient functionality.

Caution
The product must be disposed after usage in accordance with local regulations for contaminated materials.

Store product protected from light.

Store dry.

Store at ambient temperature: + 4°C to + 25 °C.

Instruction for use for recommendation.

No diving

No snorkeling

No travelling by plane

No treatment with N_2O

No mountaineering

Restrictions valid until

Information as of: | Stand der Information: | Informations en date de : | Información de: | Informazioni valide al: | Informatie per: | Informace ke dni: | A tájékoztató összeállításának időpontja: | atualizado das informações: | Informacja począwszy od: | Информация по состоянию на: | Ημερομηνία σύνταξης των πληροφοριών: | Informații din data de: | Information från den:

04/2024

INSTRUCTION FOR USE **EN**
ophthafutur® sf6 (0512)
ophthafutur® c2f6 (0513)
ophthafutur® c3f8 (0514)

Composition and Characteristics:
ophthafutur® sf6/c2f6/c3f8 contains a colorless and odorless gas, which is chemically and physiologically inert. **ophthafutur® sf6/c2f6/c3f8** is provided as a kit consisting of two sets: a gas reservoir (set 1) and a mixing device (set 2). The complete kit allows an easy, quick and safe handling. **ophthafutur® sf6/c2f6/c3f8** is used after a complete vitrectomy. Chemical composition, physical properties and initial purity: Table A
For customer convenience, an approved and CE-certified injection cannula is included in the final product.

Content and Sterilization:
ophthafutur® sf6/c2f6/c3f8 is supplied in a glass reservoir with sufficient amount to prepare 50 ml of a non-expansible gas/air mixture.
Exterior sterilization: steam sterilization

Intended purpose and Indications:
ophthafutur® sf6/c2f6/c3f8 is used as a mid-term tamponade after operative treatment:
- of severe retinal detachment, particularly for
  - retinal detachments in case of proliferative vitreoretinopathy (PVR),
  - retinal detachments with giant tears (GRT),
  - retinal detachments without proliferation,
  - retinal detachments in case of proliferative diabetic retinopathy (PDR),
- as well as of traumatic retinal detachments,
- and in case of macular holes.

This medical device is introduced into the vitreous cavity of the eye to tamponade the retina by its physical properties, mainly by its interfacial tension. It is used in operation theatres.

Intended User:
ophthafutur® sf6/c2f6/c3f8 is solely intended for the use by healthcare professionals, specifically ophthalmic surgeons or trained stuff (e.g., nurse) who are familiar with the use of such a product, and not for lay persons (patient) use according to MDR, Article 2 (37).

Administration and Dosage:
The device may only be used by an experienced surgeon. The necessary dose of **ophthafutur® sf6/c2f6/c3f8** differs in each specific case and has to be determined intraoperatively by the ophthalmic surgeon.
Prior to use, the vitreous body has to be removed completely. The retention of moisture in the eye or alternatively a humidification of the gas is recommended. The injection of the gas has to be performed slowly.
It is intended to prepare a non-expansible mixture of **ophthafutur® sf6/c2f6/c3f8** and air (Table A) prior to use following the nonverbal instruction form of this booklet (0 – 8).
The preparation of other gas concentrations can be done accordingly, whereas preparation and use are solely in the responsibility of the surgeon. The final volume after complete expansion of expansible mixtures is listed in Table A.
The gas and the air for the final gas mixtures have to be filtered through a sterile 0.2 µm filter prior to use (refer to the nonverbal instruction of this booklet). This is done during the preparation for the mixing. Therefore, the filter of the mixing device may not be removed before the mixing process is completed (4 – 7).
After mixing is finished, the required cannula with a protective cap or alternatively other systems for application having a luer connector can be attached (8). To avoid uncontrolled gas loss, any handling of unsealed gas containing components has to be performed with the opening pointing upwards at any time. After injection, there is a spontaneous displacement of the gas bubble by body fluids. Retention time of **ophthafutur® sf6/c2f6/c3f8**: Table A. **ophthafutur® sf6/c2f6/c3f8** is being exhaled within this period. Follow-up of IOP (intraocular pressure) is mandatory.

Contraindications:
Anesthesia using N_2O must be interrupted at least 20 min before applying SF_6/C_2F_6/C_3F_8.
No treatment with N_2O or hyperbaric oxygen is allowed before the gas bubble has completely disappeared.
Nd:YAG laser treatment must not be performed in gas-filled eyes.
Patients having a gas tamponade must not be exposed to pressure variations (restrictions especially but not limited to no travel by air, no diving, no snorkeling, no mountaineering, and not using fast elevators).
Patients with inability to maintain the therapeutic position, with uveitis, with severe peripheral retinal degeneration have to be excluded from a treatment with **ophthafutur® sf6/c2f6/c3f8**.
ophthafutur® sf6/c2f6/c3f8 is contraindicated in patients with hypersensitivity to fluorinated gases (sulphur hexafluoride/hexafluoroethane/octafluoropropane).

Adverse Reactions and Undesirable Side Effects
In relation to surgical repair of retinal detachment and/or macular holes with intraocular gas endotamponade (SF_6, C_2F_6, C_3F_8), the following potential complications have been reported: temporary and chronic IOP alterations including secondary glaucoma, cataract, and corneal complications.
Intracranial gas migration is a rare complication of retinal detachment repair with intraocular gas, which may occur in the setting of structural defects of the optic nerve and high postoperative intraocular pressure.
Unexplained visual loss is a rare complication of retinal detachment repair with intraocular gas endotamponade, which has been reported with perfluoropropane (C_3F_8).
As well, vascular and/or structural changes in the retina have been reported after surgical repair with intraocular gas endotamponade (SF_6, C_2F_6, C_3F_8).

Interactions:
There are no interactions known.

Warnings and precautions:
ophthafutur® sf6/c2f6/c3f8 is only intended for surgery of the posterior segment of the eye and should only be used as an ocular endotamponade according to its intended use. **ophthafutur® sf6/c2f6/c3f8** is solely intended for the use by healthcare professionals, specifically ophthalmic surgeons or trained stuff (e.g., nurse) who are familiar with the use of such a product and not for lay persons (patient) use according to MDR, Article 2 (37).
The selection of patients, of the operation methods, and of the dose of the endotamponade are the sole responsibility of the ophthalmic surgeon. The necessary dose of **ophthafutur® sf6/c2f6/c3f8** differs in each specific case and has to be determined intraoperatively by the ophthalmic surgeon. It is intended to prepare a non-expansible mixture of 20% SF_6 + 80% air/16% C_2F_6 + 84% air/12% C_3F_8 + 88% air prior to use. The preparation of other gas concentrations can be done accordingly but preparation and use are solely in the responsibility of the surgeon. Depending on administration (expansible or non-expansible mixture) the gas bubble may change in volume. Expansible mixtures are completely expanded to the double/triple (3.3)/fourfold of the initially injected volume after 48/60/96 hours. Follow-up of IOP (intraocular pressure) is mandatory.
Prior to use, the vitreous body has to be removed completely. The gas and the air for the final gas mixtures have to be filtered through a sterile 0.2 µm filter prior to use (refer to the nonverbal instruction of this booklet). This is done during the preparation for the mixing. Therefore, the filter of the mixing device may not be removed before the mixing process is completed. The retention of moisture in the eye or alternatively a humidification of the gas is recommended. The injection of the gas has to be performed slowly. To avoid uncontrolled gas loss, any handling of unsealed gas containing components has to be performed with the opening pointing upwards at any time. After injection, there is a spontaneous displacement of the gas bubble by body fluids over a period of up to 14/35/65 days. The SF_6/C_2F_6/C_3F_8 is being exhaled within this period. Follow up of IOP is mandatory.
Do not use the product after its expiry date. The expiry date is based on the storage conditions below. Do not use the product if the packaging is opened or damaged or if you have doubts about the sterility of the product. Opened product should not be kept for later use. The kit is for single use only. The following risks can arise from unauthorized reuse: Infection due to insufficient sterility and/or biological contamination. Reuse can lead to invisible damage to the device and thus to insufficient functionality. Re-processing and re-sterilization of **ophthafutur® sf6/c2f6/c3f8** are not permitted. The following risks can arise from unauthorized reprocessing and re-sterilization: Infection due to insufficient sterility and/or biological contamination. Reprocessing can lead to invisible damage to the device and thus to insufficient functionality.
In order to assist with communication, a patient information card and a bracelet as well as an implant card are provided with this product and should be given to the patient.
Avoid the inhalation of SF_6/C_2F_6/C_3F_8 which can result in apnoea or CO_2 anesthesia.
ophthafutur® sf6/c2f6/c3f8 should be stored at room temperature (store dry at 4 °C – 25 °C) and protected against light and frost.

Summary of Safety and Clinical Performance
https://ec.europa.eu/tools/eudamed

Adverse Reaction Reporting:
Adverse reactions, serious incidents and/or potentially sight threatening complications may be reasonably regarded as **ophthafutur® sf6/c2f6/c3f8** related and that were not previously expected in nature, severity or degree of incidence. These should be reported to Pharmpur GmbH at vigilance@pharmpur.de. and the competent authority of the member states, in wich the user and/or patient is established.

Storage:
ophthafutur® sf6/c2f6/c3f8 should be stored at room temperature (store dry at 4 °C – 25 °C) and protected against light and frost.

Shelf life:
3 years. **ophthafutur® sf6/c2f6/c3f8** must not be used after expiration date.

Disclaimer of Liability:
Pharmpur GmbH is not liable for any use of the product, which does not comply with these instructions for use, or for use outside the product's intended purpose. In particular, Pharmpur GmbH is not responsible for damage caused by the application of an improper use (refer to sections "adverse reactions and undesirable side effects", "interactions", and "contraindications").

Table A	ophthafutur sf6	ophthafutur c2f6	ophthafutur c3f8
Chemical composition	SF_6	C_2F_6	C_3F_8
CAS number:	2551-62-4	76-16-4	76-19-7
Density (1 bar):	6.07 kg/m³ [20 °C]	5.84 kg/m³ [15 °C]	8.17 kg/m³ [15 °C]
Density ratio to air:	5.1	4.8	6.5
Initial purity:	99.995 %	99.999 %	99.99 %
Non-expansible mixture:	20 % SF_6 + 80 % air	16 % C_2F_6 + 84 % air	12 % C_3F_8 + 88 % air
Retention time:	up to 14 days	up to 35 days	up to 65 days
Expansible gas/gas mixture			
Factor of volume expansion:	2	3.3	4
Completely expanded after:	48 hours	60 hours	96 hours

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Germany

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Fax: +49 8231 9577-22

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