

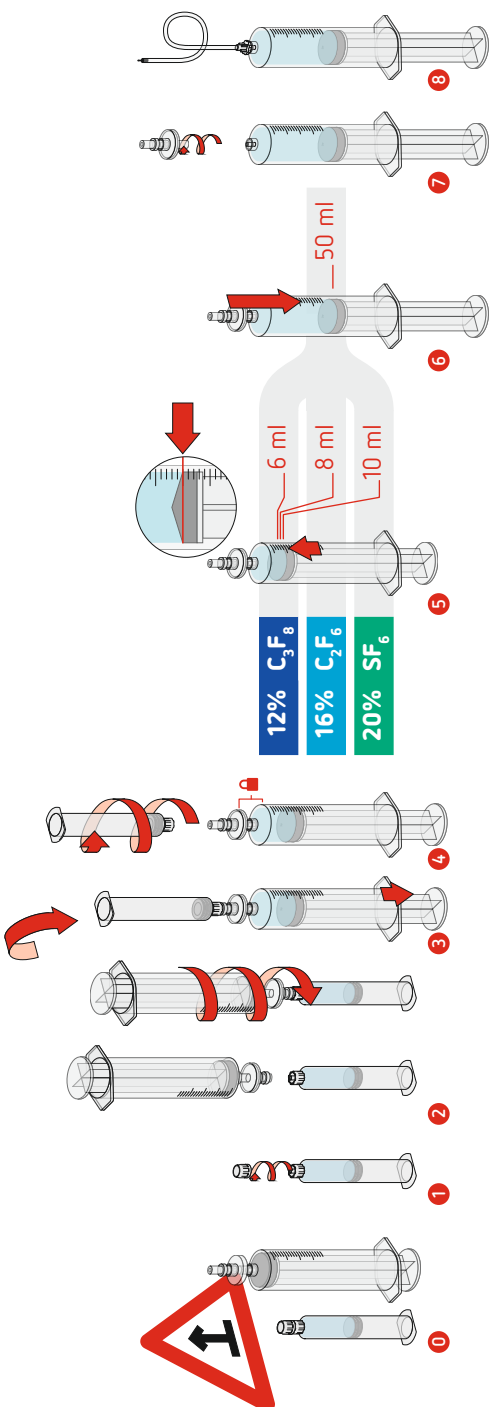
ophtha futur[®]

sf6

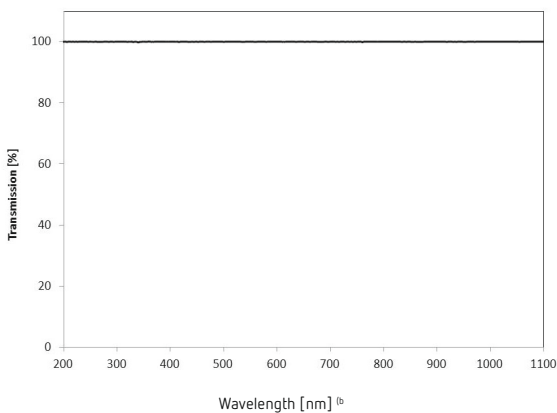
c2f6

c3f8

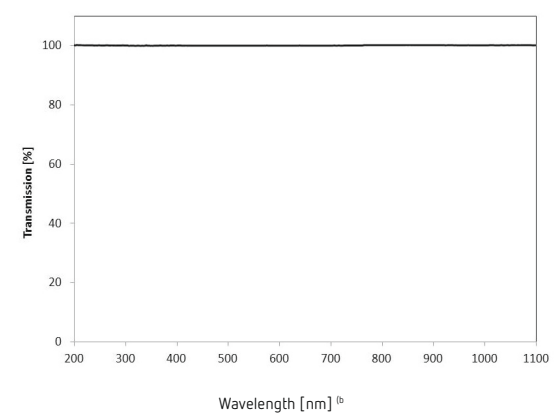
Nonverbal instruction |
Grafische Anleitung |
Instructions non verbales |
Instrucciones no verbales |
Istruzione non verbale |
Non-verbale instructies |
Neverbální instrukce |
Nonverbális utasítása |
Niewerbalne wskazówki |
Невербальной инструкции



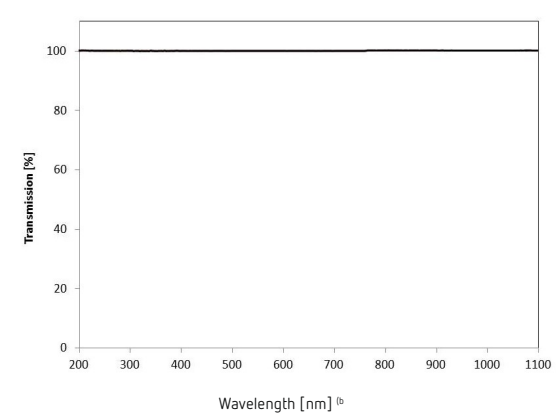
Curve of Spectral Transmittance ^(a)

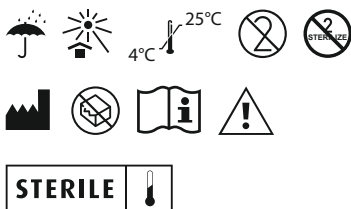
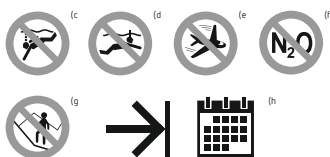


Curve of Spectral Transmittance ^(a)



Curve of Spectral Transmittance ^(a)





CE
0297

(a 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 | Spekt-rális Áteresztési Görbe | Krzywa Transmitancji Widmowej | Кривая Спектрального Коэффициента Пропускания

(b Wavelength | Wellenlänge | Longueur d'onde | Longitud de Onda | Lunghezza d'onda | Golflengte | Vlnová Délka | Hullámhossz | Długość Fali | Длина Волны (нм)

(c No diving | Nicht Tauchen | Plongée interdite | Prohibido el buceo en profundidad | No immersioni | Niet duiken | Nepotápět se | Tilos a vízbe ugrás | Zakaz swobodnego nurkowania | Не нырять

(d No snorkeling | Nicht Schnorcheln | Plongée avec tuba interdite | Prohibido el buceo de superficie | No snorkeling | Niet snorkelen | Nešnorchlovat | Tilos a búvárkodás | Zakaz nurkowania z falką | Не плавать с дыхательной трубкой

(e No travelling by plane | Keine Flugzeugreisen | Voyages en avion interdits | Prohibido viajar en avión | No viaggi in aereo | Niet vliegen | Necestovat letadlem | Tilos a repülőgépes utazás | Zakaz lotów samolotem | Не путешествовать самолетом

(f No treatment with N₂O | Keine Behandlung mit N₂O | Traitement au N₂O interdit | Prohibido el tratamiento con N₂O | Nessun trattamento con N₂O | Niet behandelen met N₂O | Neléčit pomocí N₂O | Tilos N₂O-val kezelni | Zakaz podawania N₂O | Не лечить N₂O

(g No mountaineering | Nicht Bergsteigen | Alpinisme interdit | Prohibido el montañismo | No alpinismo | Niet bergbeklimmen | Neprovazovat horolezectví | Tilos a hegymászás | Zakaz wspinania się po górach | Нет заниматься альпинизмом

(h Restrictions valid until | Einschränkungen gültig bis | Les restrictions restent valables jusqu'au | Restricciones válidas hasta | Restrizioni valide fino a | Beperkingen gelden tot | Omezení platí do | A korlátozások a következő időpontig érvényesek | Ograniczenia obowiązują do | Нет заниматься альпинизмом

Information as of: | Stand der Information: | Informations en date de : | Informaciónde: | Informazioni valide al: | Informatie per: | Informace ke dni: | A tájékoztató összeállításának időpontja: | Informacja począwszy od: | Информация по состоянию на:

09/2018

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.

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), for retinal detachments with giant tears, retinal detachments without proliferation, retinal detachments in case of proliferative diabetic retinopathy (PDR), traumatic retinal detachments, macular holes and macular edema.

Application 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 recommended 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/or gas mixtures have to be filtered through a sterile 0.2 µm filter prior to use. 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 the ophthafutur sf6/c2f6/c3f8: Table A. The ophthafutur sf6/c2f6/c3f8 is being exhaled within this period. Follow up of IOP (intraocular pressure) is mandatory.

Contraindications and adverse reactions:

Anesthesia using N₂O must be interrupted at least 20 min before applying ophthafutur sf6/c2f6/c3f8. No treatment with N₂O 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 (especially but not limited to flying, diving and 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.

The occurrence of cataract, corneal defects, or secondary glaucoma has been reported.

Interactions:

There are no interactions known.

Warnings and precautions:

Do not use the product after its expiry date.

Avoid the inhalation of ophthafutur sf6/c2f6/c3f8 which can result in apnoea or CO₂ anesthesia.

The kit is for single use only. Repeated use can lead to microbiological contaminations which may result in severe infections or inflammation of the patients.

In order to assist with communication, a patient information card and a bracelet are provided with this product and should be given to the patient.

Depending on administration (expansible or non-expansible mixture) the gas bubble may change in volume.

Storage:

Store the product at room temperature (store dry at 4 °C – 25 °C) and protect against sunlight.

Shelf life:

2 years. ophthafutur sf6/c2f6/c3f8 must not be used after expiration date.

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.

Table A

	ophthafutur sf6	ophthafutur c2f6	ophthafutur c3f8
Chemical composition	SF ₆	C ₂ F ₆	C ₃ F ₈
CAS number:	2551-62-4	76-16-4	76-19-7
Density (1 bar):	6.07 kg/m ³ [20 °C]	5.84 kg/m ³ [15 °C]	8.17 kg/m ³ [15 °C]
Density ratio to air:	5.1	4.8	6.5
Initial purity:	99.995 %	99.999 %	99.99 %
Non-expansible mixture:	20 % SF6 + 80 % air	16 % C2F6 + 84 % air	12 % C3F8 + 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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