



FLUORON® GmbH • Magirus-Deutz-Str. 10 • 89077 Ulm • Germany

28 November 2014

Important Safety Notice

Recall of the Gas Tamponade EasyGas SF₆

Attention all distributors and users of the following products

- EasyGas SF₆ Lot-Nr. EG1 300614 Ref.-No.: G-80950
- EasyGas SF₆ Lot-Nr. EG1 150714 Ref.-No.: G-80950

Dear Sir or Madam,

According to our information you received one of the above-mentioned products.

In individual cases it might be possible that during the production of the above-mentioned products C₃F₈ (12%) was filled instead of SF₆ (20%). For safety reasons we have decided to recall the product with the lot numbers EG1 300614 and EG1 150714. The concentration of C₃F₈ (12%) is non-expansile.

Concerning the underlying diagnosis there are no additional risks for the patient by applying C₃F₈ (12%), but **IOP should be monitored at close intervals**. Patients who have recently received a gas tamponade of the above-mentioned lot numbers need to have a corresponding follow-up. Furthermore, there is an extended effective tamponade time (30 days in the case of C₃F₈ compared to 6 days in the case of SF₆) and retention time within the eye (exhaled over a period of up to 60 days for C₃F₈ compared to a period of up to 15 days for SF₆), respectively. Correspondingly, this results in **extended limitations for activities involving pressure variations (e.g. air travel or stay at high-altitude) and the well-known prohibition of anaesthesia using nitrous oxide** for a period of 60 days from treatment.

Immediately stop the application and sales of the products with the above-mentioned lot numbers.

FLUORON® GmbH
Gesellschaft für hochreine Biomaterialien
Geschäftsführer: Volker Geuder
Amtsgericht Ulm HRB 723852
USt-IdNr.: DE812135435

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Zertifiziert nach DIN EN ISO 9001 / 13485

Immediately Necessary Measures

- **Quarantine all lots of the above-mentioned product still in your organization.**
- **Return these lots to Fluoron GmbH according to the procedure given below.** Please send us a written confirmation that all products of the respective lots in stock were returned to FLUORON GmbH under specification of quantity and date. Please choose among 'replacement delivery' and 'credit voucher'.
- Please ensure that all users of the above-mentioned products and persons for whom this important safety notice is relevant are informed. This is particularly important to **take the appropriate steps for patient follow-up**. If you have transferred these products to third parties, please forward a copy of this safety notice to them or notify the contact person mentioned below.
- **Please immediately inform all patients who have received the above-mentioned products** about the resulting extended limitations for activities involving pressure variations (e.g. air travel or stay at high-altitude) and the prohibition of anaesthesia using nitrous oxide for a period of 60 days from treatment.

Please keep this safety notice until all measures have been completed.

RETURN DELIVERY :

Please return your delivery to:

Fluoron GmbH
Dr. Wilfried Kugler
Magirus-Deutz-Straße 10
89077 Ulm
Germany

Should you need any further information or support, please contact Fluoron GmbH,
Phone +49 731 20 55 997 33 or FAX + 49 731 20 55 997 28.

This notice was delivered to the competent authorities.

We apologize for this incident and any inconvenience this has caused.

Yours sincerely,



Fluoron GmbH

p.p. Dr. Wilfried Kugler
Safety Officer



RECALL of the FLUORON GAS TAMPONADES

- EasyGas SF₆ Lot-Nr. EG1 300614 Ref.-No.: G-80950
- EasyGas SF₆ Lot-Nr. EG1 150714 Ref.-No.: G-80950

Dear Sir or Madam,

We confirm that we have stopped sales of the above-mentioned EasyGas products as of now, according to your safety information dated 28 November 2014. EasyGas products still in stock and returned to us, respectively, will be sent back to you immediately.

Lot number EasyGas	Quantity
EG1 300614	
EG1 150714	

We would kindly like to ask you for a

replacement delivery

credit voucher

Yours sincerely,

(stamp, date and legally binding signature)

EasyGas C₃F₈

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EasyGas C₃F₈ is a colourless, odourless and biocompatible gas mixture that is made up of 12% octafluoropropane (C₃F₈), minimum purity 99.95 %, in air. C₃F₈ is chemically and physiologically inert and has a density of 7,990 kg/m³. The Ready-to-Use system of Fluoron GmbH is characterised by its easy, quick and safe handling. EasyGas C₃F₈ is used after vitrectomy is complete.

Indications

EasyGas C₃F₈ is used as a long-term tamponade after operative treatment of severe retinal detachment, particularly for proliferative vitreoretinopathy (PVR).

Composition

12 % octafluoropropane (minimum purity 99.95 %) and 88 % air

Physical properties C₃F₈

Density	[kg/m ³ at 15 °C]	7.990
Relative density relative to dry air (15 °C, 1 bar)	[kg/m ³ at 15 °C]	6.610
Solubility in water		immiscible
Vapour pressure	[bar at 20 °C]	7.7

Operating instructions

Before using EasyGas C₃F₈, the plug and syringe filter must be removed and the required cannula, with its protective cap, attached. After completed vitrectomy EasyGas C₃F₈ is used as an agent for medium to long-term tamponades. The gas is completely expanded after about 72 hours and is not removed but is exhaled over a period of up to 60 days and displaced by bodily fluids.

Contraindications

There are no contraindications known when used in accordance with the recommendations.

Adverse reactions

When using gases there can be expansion of the gas beneath the retina or the conjunctiva as well as fragmentation or inclusion of the gas in the pars plana or the lens.

Instructions for use

Before using EasyGas C₃F₈, the syringe filter must be removed.

Form of administration

EasyGas C₃F₈ is supplied in a ready-to-use system with a filling volume of 40 mL.

Storage conditions

Store EasyGas C₃F₈ at room temperature. Avoid large pressure and temperature fluctuations.

Sterilisation

Gamma sterilization

Warnings

Before applying EasyGas C₃F₈ first ensure that the vitreous body has been completely removed. Patients with a gas tamponade must not be exposed to pressure variations (flying, diving, etc.). Anaesthesia using nitrous oxide must be interrupted at least 20 minutes before applying EasyGas C₃F₈. Do not use this product if the sterilization indicator adhered to the sterilisation bag has not changed colour from orange to red or if the expiry date has passed. The expiry date is shown on the packaging. Only use undamaged packages. Syringes are only intended for single use on one patient. Repeated use can lead to microbial contamination of the product, which may result in severe infections in the patient.

Explanation of symbols



only for single use



sterile



see operating instructions



expiry date