

Sulphur hexafluoride - Pure or mixed with nitrogen to 20%, single use/multi-dose, for a prolonged use ETO sterilized package – Content to be filtered with filter included

Indications

The MicroSF6 is a high molecular weight gas used to replace the vitreous during vitrectomy surgery with a medium time of permanence in the eye no longer than 7 days.

Contraindications

Do not inject into the vitreous.

Classification

Medical device class IIb.

Use

The device must be used in a sterile field only by a vitreo-retinal skilled surgeon. The MicroSF6 is inserted in the vitreous cavity after having removed with care the central and peripheral vitreous as it is indeed considered a risk to infuse gas directly into the vitreous. Before the infusion, it is recommended anyway to ensure that there is no free vitreous or vitreous that can be pushed by the gas in anomalous positions, especially in aphakic eyes. It is possible to infuse gas either with a blunt cannula or with the help of a special connector through the infusion cannula inserted in the sclera and normally used to infuse physiologic solution in the eye during vitrectomy. Due to the fact that it is practically impossible to check if the intraocular pressure is correct (20-40 mmHg.), during the infusion, it is necessary to ensure the correct pupil sprinkling and the possible compression of the optic

nerve. In this case infusion should be interrupted immediately. If the eye is sealed, ensure that there is a way out during the injection of the product to avoid a potentially dangerous ocular hypertension. Constantly check the papilla, during infusion, to ensure that there is a correct veins sprinkling.

Composition

The MicroSF6 is constituted by SF6 Sulphur hexafluoride pure to 99.90%

Formula	[SF ₆]
Molecular weight	146
Melting point	-50,8 °C
Boiling point	-64 °C
Relative density, as gas	5
Relative density, as liquid	1,4
Vapor pressure @ 20 °C	21 bar
Solubility in water	41 mg/l
Appearance	colorless
Odor	none
CAS Nr.	02551-62-2
CEE Nr.	219-854-2

MMD-781 (MicroSF6 pure)

Packaging

50ml canister filled with MicroSF6 pure for ophthalmic use, 50ml infusion syringe, filter, three-way cock, 27G e 30G needles, plastic wristband for the patient.

Method of Usage

Before infusion, the gas must be sterilized through the filter; the other accessories included in the package are already sterilized with EtO. Check that the package is intact.

When using a pure gas it is necessary to prepare a mixture with air before starting the infusion, this is done directly in the syringe as follows:

- connect the filter to the syringe at the side of the Luer female connector
- connect the filter to the adapter already mounted on the canister by the manufacturer
- push the syringe towards the canister to fill it with a small quantity of gas (about 5ml)
- empty the syringe and fill it again with a quantity of gas enough to override the 20% indication

- push the piston towards position [1] in order to meet the level of desired kind of mixing (15% or 20%), thus expelling gas in excess
- then aspire air pulling the piston towards position [2] corresponding to 100%
- during these operations the filter MUST NOT BE removed from the syringe
- remove the filter when finished and proceed to the infusion.



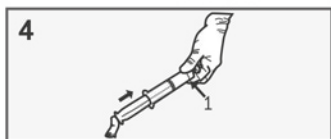
connect the filter to the syringe



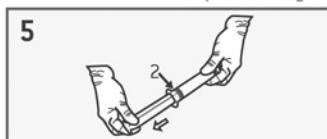
insert the syringe-filter assembly on the adapter mounted on the canister



push the syringe against the canister to fill it with an adequate amount of gas



push the plunger in position [1] corresponding to the desired value of mixing, so expelling the excess gas



then aspirate air, pulling the plunger at the position [2], indicated with 100%

MMD-780 (MicroSF6 mixed with nitrogen to 20%)

Packaging

50ml canister filled with MicroSF6 pure for ophthalmic use, mixed with nitrogen to 20%, 50ml infusion syringe, filter, three-way cock, 27G e 30G needles, plastic wristband for the patient.

Method of Usage

Before infusion, the gas must be sterilized through

the filter; the other accessories included in the package are already sterilized with EtO. Check that the package is intact. The syringe is filled with the gas contained in the small canister following this procedure:

- connect the filter to the syringe at the side of the Luer female connector
- connect the filter to the adapter already mounted on the canister by the manufacturer
- push the syringe towards the canister to fill it

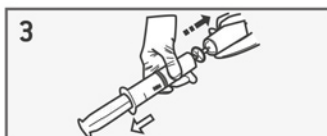
- with a small quantity of gas (about 5ml)
- empty the syringe and fill it again to full capacity of 50ml
- during these operations the filter MUST NOT BE removed from the syringe
- remove the filter when finished and proceed to the infusion.



connect the filter to the syringe



insert the syringe-filter assembly on the adapter mounted on the canister



push the syringe against the canister to fill it with an adequate amount of gas



WARNINGS

- Patients who have undergone such procedure must not travel by air or exceed the altitude at which the procedure has occurred for the first four days following the infusion
- In case of anesthesia with nitrous oxide the inhalation must be suspended at least 15 minutes before employment of SF6
- Expandable gas is injected in the eye. Check ocular pressure every hour after the procedure for the first 6 hours and frequently for the next 36 hours
- Remember to apply the plastic wristband included in the package.
- If the pressure rise more than 30 mmHg reduce the gas contained in the bulb. The same if the patient complains of pain. That procedure must be performed suddenly, not more than 10 minutes after pain
- BE CAREFUL IF THE GAS IS USED AS PURE !!! It is reminded that the suggested concentration of SF6 gas is about 20%