MICROC3F8

1. INSTRUCTIONS

MicroC3F8 is a class IIb implantable medical device. It is a high molecular weight gas used in vitrectomy, ab-external surgery and pneumatic retinopexy. The product is intended to replace the vitreous humor and has an average residence time in the eye of 6-8 weeks.

2. INFORMATION REQUIRED BEFORE USING THE DEVICE

This medical device must be used by medical professionals, and ophthalmologists experienced in vitreous-retinal surgery, in a sterile field

It is possible to infuse the gas either with a blunt cannula or with the aid of the special inserter, through the cannula inserted into the sclera and normally used to infuse saline solution into the eye during the vitrectomy

Warnings and Precautions:

- Do not use the device for purposes other than those indicated
- This medical device is single-use. The presence of multi-doses is intended only as a precautionary measure, to provide a back-up in case of procedural problems in the operating room.
- Use only in sterile field
- Do not use the product after the expiry date
- Make sure the packaging is intact: sterility is guaranteed only if the packaging is intact. Do not use the device if the packaging is damaged
- Do not re-sterilise the accessories. Re-sterilisation could lead to material degradation processes
- The accessories contained are sterile and single-use only. Reuse of the accessories can lead to bacterial contamination events, with serious consequences for the patient
- The gas in the canister is NOT sterile. Sterilise with the filter provided
- Pure gas must be mixed with sterile air: the suggested concentration for C3F8 is in the 12% range
- Make sure that there is no free vitreous or that it can be pushed by gas into abnormal positions; especially in aphakics,
- check for correct papillary blood supply and any compression of the optic nerve and, if necessary, immediately stop the infusion
- If the eye is leaky, ensure that there is a way of venting while injecting the substance, to avoid dangerous ocular hypertension
- In case of hypertone >30 mmHg, reduce the gas contained in the bulb directly within 10 minutes.
- The injected gas is an expandable mixture: check the eye pressure every hour for the first 6 hours and frequently for the next 36 hours
- Any use of infusion machines should be limited to equipment approved for ophthalmic use. It is the physician's responsibility to verify compatibility between the device and the equipment specifications.

Contraindications

Do not inject into the vitreous
In the case of anaesthesia with nitrous oxide, inhalation of anaesthetic must be discontinued at least 15 minutes before using the product

Recommendations

- Inform the patient of all the correct behaviours to follow

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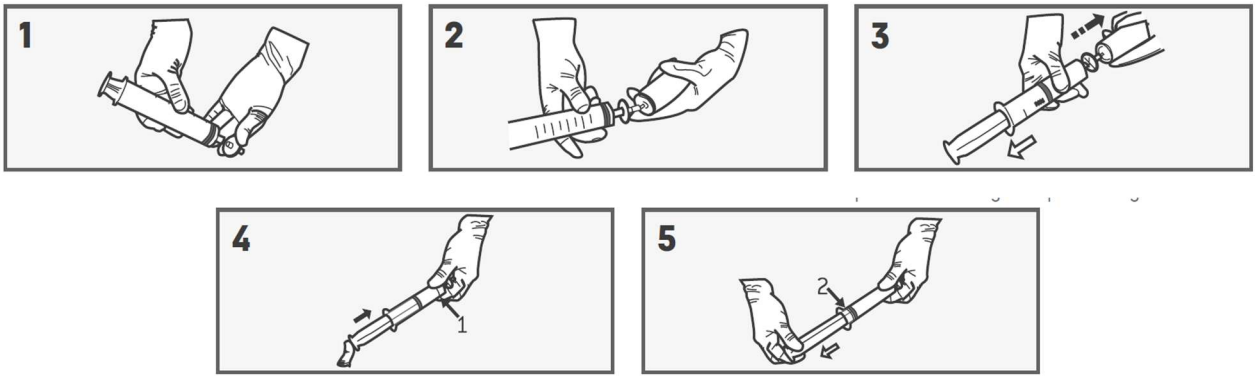
- To avoid dangerous ocular hypertension, patients should not expose themselves to pressure variations, such as travelling by plane, to the mountains at high altitudes or diving; special attention should also be paid to sudden changes in environmental temperature (e.g. entering an overheated car in summer)
- Fill in and give the implant card to the patient
- Attach the bracelet to the patient's wrist

3. HOW TO USE

MMD-788 - Pure MicroC3F8

It is necessary to prepare the mixture with air, before proceeding with the infusion procedure; this is done directly in the syringe, by proceeding as follows:

- connect the filter to the syringe from the female luer inlet fitting side
- fit the filter on the canister
- push the canister to fill the syringe with a small amount of gas (approx. 5ml)
- empty the syringe and refill it with enough gas to cross the line marked as 12%
- push the plunger to position (1) at the suggested mixing value (20%), to expel any excess gas
- suck in the air, bringing the plunger to position (2) indicated by 100%
- never remove the filter from the syringe during these operations
- remove filter once the syringe is full and proceed to use.



MMD-787 - MicroC3F8 in 12% nitrogen mixture

The supplied syringe is filled with the gas contained in the canister by performing the following steps:

- connect the filter to the syringe from the female luer inlet fitting side
- fit the filter on the canister
- push the canister to fill the syringe with a small amount of gas (approx. 5ml)
- empty the syringe and refill it again completely, up to 50ml
- never remove the filter from the syringe during these operations.
- remove filter once the syringe is full and proceed to use.

4. POSSIBLE ADVERSE EFFECTS

Vitreoretinal surgery can lead to post-operative complications.
Some of the post-operative complications could be:

- Neovascular glaucoma
- Cataract
- Lenticular opacity
- Keratopathies
- Hypertone (increased eye pressure)
- Transient or permanent decrease in eye pressure, evolving towards bulbar phthisis
- Macula alterations
- Choroid detachment
- Retinal tear and/or relapsed retinal detachment

It is the surgeon's responsibility to properly inform the patient about the risks and benefits of the surgery.

REPORTING ACCIDENTS AND ADVERSE EFFECTS

In case of uncommon incidents and/or adverse effects observed after using the Microgas product, the health care professional is strongly encouraged to report the event to the manufacturer using the e-mail address: incidentiereclami@micromed.it. In the report, describe the event in detail and indicate the batch number used.
If you have any complaints or feedback about the product, please send an email to incidentiereclami@micromed.it.

5. STORAGE

The bottle contains pressurised gas. The product may explode if heated due to increased pressure: the gas is neither flammable nor toxic.
Store at room temperature, in a cool, dry place, away from direct sunlight.
Do not use the product if the inner packaging that guarantees sterility is not intact.
Do not use the product after the expiry date.
Dispose of the product as hospital waste.

6. PACKAGE CONTENTS AND AVAILABLE FORMATS

Each Microgas pack contains: 50ml bottle of MicroC3F8, sterilising filter, 50ml infusion syringe, three-way valve, 27G and 30G needles, implant card and plastic patient wristband.
The MicroC3F8 product is available in two variants:

- Pure (art. no. MMD-788)
- Mixed with 12% nitrogen (art. no. MMD-787)

Chemical and physical properties of C3F8 gas (purity ≥ 99.96%)

Formula	[C3F8]
Molecular weight	188
Melting point	-183 °C
Boiling point	-36.7 °C
Relative gas density	6.5
Relative liquid density	1.4
Vapour pressure at 20ºC	7.7 bar
Water solubility	ND
Appearance: Gas	(colourless)
Smell	ether
CAS No.	76-19-7
EEC no.	200-941-9

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7. MANUFACTURER'S DATA

The manufacturer of the Microgas medical device is
Micromed Srl
Registered Office: Viale Val Padana, 126 - 00141 - Rome - Italy
Production Site: Via Oberdan, 21 - 00013 - Fonte nuova (Rome) - Italy
For information, please write to: info@micromed.it
For incidents, complaints and feedback, please write to: incidentiereclami@micromed.it
The MicroC3F8 medical device is CE 0373 certified.

8. SYMBOLS

Symbol	Description
	Manufacturer
	Product code
	Batch number (REF-SSAA)
	Date of manufacture (YYYY-MM)
	Expiry date (YYYY-MM)
	Ethylene Oxide sterilised
	Single-use device
	Does not contain latex
	Caution: read the package leaflet carefully
	Do not re-sterilize
	Do not use if package is open or damaged
	Pressurized gas
	Keep away from sunlight
	Store in a dry place
	UDI (AIDC format) - GS1 - DataMatrix (1) UDI-DI (17) Expiry date (10) Batch number

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