VIAL PFCL

1. INSTRUCTIONS

PFCL - Perfluoro Carbide Liquid - is a class IIa medical device. It is a high-density, low-viscosity liquid intended for vitreous chamber tamponade during eye surgery, with a maximum residence time in the eye of 1 hour. After removal, it can be replaced with a long-term buffering medium.

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.

PFCL is used for vitreous chamber tamponade, after removal of the central and possibly peripheral vitreous body. Its use is limited to the duration of surgery and once it has performed its action, it must be removed. Its low viscosity allows for easy infusion into the eye using standard instrumentation.

Warnings and Precautions:

- Do not use the device for purposes other than those indicated
- This medical device is single-use.
- 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
- Make sure that there is no free vitreous that can mix with PFCL
- If the eye is under continuous infusion, ensure that PFCL does not flow back along the infusion line
- Make sure that there is a way of venting while injecting the substance, to avoid ocular hypertension
- After washing and removing the liquid and solid residues, remove the substance from the eye within one hour. The residence time in the eye should be less than 60 minutes.
- Perfluorocarbons cannot be mixed with silicone oil.

Contraindications

- Do not inject into the vitreous
- Do not use as a vitreous substitute
- Do not leave in situ under any circumstances.

Recommendations

- Check the optic papilla during infusion to ensure that the vessels are properly supplied with blood
- Before injecting, completely free the retina from traction to avoid iatrogenic retinal breaks, and check for posterior breaks to avoid subretinal passage of the substance.
- The injection of liquid perfluoro carbonate is performed manually, by gradually filling the vitreous chamber and completely evacuating the subretinal fluid
- There is no need to fill the vitreous chamber completely; however, the front level of the bubble that the PFCL forms in the vitreous chamber must stop behind the rear limit of the vitreous base, to allow better vision during peripheral manoeuvres and reduce the danger of subretinal passage of the fluid
- After surgery, position the patient correctly, and perform adequate postoperative care

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3. HOW TO USE

- open the PFCL package and remove the seal leaving the capsule closed
- Clean the exposed rubber of the cap with alcohol
- using a needle inserted into the cap with a sterile syringe, withdraw the required quantity
- replace the 18G needle with the 25G long needle, insert through a pars-plane sclerotomy and inject slowly.

4. POSSIBLE ADVERSE EFFECTS

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

- Formation or advancement of cataracts
- Hypertone (increased eye pressure)
- Transient or permanent decrease in eye pressure Acute glaucoma
- Optic nerve damage
- Lens injury
- Retinal haemorrhage
- Visual field defects.

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 the event of an accident and/or adverse effect occurring as a result of the use of the PCFL product, the healthcare professional must report the event to the competent authority of the Member State in which it occurred, to the distributor and to the medical device manufacturer (incidentiereclami@micromed.it). In the report, describe the event in detail and indicate the UDI code of the device involved.

If you have any complaints or feedback about the product, please send an email to incidentiereclami@micromed.it.

5. STORAGE

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 package contains one vial with perfluorine, a 10 ml syringe, a 25G needle, a 18G needle.
The product is available in 3 variants:

1. 5cc Code MMD-750
2. 7cc Code MMD-749
3. 10cc Code MMD-751

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Chemical and physical characteristics

Formula	[C10F18]
Boiling point	141-143°C
Density	1.941 g/ml @24°C
Relative molecular mass	462.08
Refractive index	1.314 @24ºC
Viscosity	2.7 centistokes @25ºC
Appearance: Liquid	(colourless)
Smell	none
CAS No.	306-94-5
EEC no.	2061924

7. MANUFACTURER'S DATA

The manufacturer of the PFCL 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 PFCL - VIAL 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
	Dry heat 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
	Keep away from sunlight
	Store in a dry place
	UDI (AIDC format) - GS1 - DataMatrix (1) UDI-DI (17) Expiry date (10) Batch number

This leaflet was updated on July 2022, revision 1.0