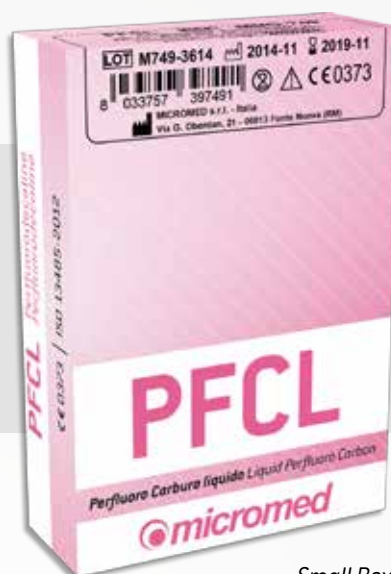


Liquid Perfluoro Carbon - octadecafluorodecahydronaphthalene
supplied in 5, 7 and 10cc in vials / 7cc precharged glass syringes

Micromed Silicones Assortment

The PFCL (Perfluorodecaline) is a high density liquid, intended to be used to wash the vitreous chamber during intervention of ophthalmic surgery, with residence time in the eye of max one hour.



Small Box for Vials and Glass Syringe

Perfluorocarbons

The perfluorocarbon liquid (PFCL) are heavy compounds with a density between 1.7 and 2.1 g/cm³.

The perfluorocarbons are colorless, non-toxic, chemically and physiologically inert and are widely used in vitreoretinal surgery for the relaxation of the retina. The surface tension and the contact are such as to avoid the risk of migration of these compounds under the retina in the case of giant tears. For this reason, the perfluorocarbon liquid are considered excellent products to relax and also re-adhere the detached retina [while the silicone oil is the product of choice for the next buffering].

The PFCL have opposite characteristics that advise against the use for a long term usage. Despite perfluorocarbons are absolutely non-toxic, the use of this compounds is only permitted during intraoperative phases, they must always be removed at the end of the surgical procedure because their stay in the eye causes retinal changes within a relatively short time.

The perfluorocarbons can not be mixed with silicone oil. For this reason, in case of buffering with silicone oil subsequent to the use of PFCL, the drops of perfluorocarbon eventually not removed, will dissolve very slowly and, if a significant quantity, may give rise to emulsions.

Usage

The PFCL must be inserted into the vitreous cavity only after having removed with care the central vitreous and in most complicated cases the peripheral vitreous. Anyhow before infusion must check that there is no free vitreous or vitreous that could mix with the PFCL itself.

Once this situation has been verified, check that there are no holes or slots on the retina in such a position that part of the material could be captured in the retinal choroid space. Aspirate the PFCL from the package and inject slowly with a blunt cannula. If the eye is sealed make sure there is a way to vent while injecting the substance in order to avoid

a dangerous ocular hypertension. You should still check the papilla, during infusion, to make sure of proper blood supply to the vessels.

If the eye is under continuous infusion, you should make sure not that the PFCL along the infusion line, because the high density of the liquid would balance the pressure infusion, leaving the bulb without tone. If that happens, it is recommended to raise the infusion pressure until all the PFCL is returned in the bulb.

Immediately after the washing and removing the liquid and solid residues, remove the substance from the eye within one hour.

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PRODUCT LINE AND CODES		
	PFCL	
Vial (Package 1)	MMD-750	5cc
	MMD-749	7cc
	MMD-751	10cc
Glass Syringe (Package 2)	MMD-747	7cc

PFCL TECHNICAL DATA	
PFCL	<i>Octadecafluorodecahydronaphthalene</i>
Formula	<i>C10F18</i>
Viscosity	<i>2.7 cSt @ 24°C</i>
Refractive Index	<i>1.314 @24°C</i>
Density	<i>1.941 gr/ml @24°C</i>
Boiling Point	<i>141-143°C</i>
Appearance	<i>Clear, colorless</i>
Sterilization	<i>See kind of Packaging</i>

KIND OF PACKAGING		
Package 1	Vial	Vial filled with 5/7/10cc PFCL Vial and its content sterilized at Dry Heat (3h @ 170°C) Envelope content (Precharged Vial, 10ml Plastic Syringe, 20G 31.3mm blunt cannula, 18G Needle) sterilized at Ethylene Oxide Small Carton Box (90x110x35)mm
Package 2	Glass Syringe	10ml Glass Syringe filled with 7cc PFCL Syringe and its content sterilized at Dry Heat (3h @ 170°C) Envelope content (Precharged Glass Syringe, luerlock adapter, 20G 31.3mm blunt cannula) sterilized at Ethylene Oxide Small Carton Box (90x130x35)mm