

# SURGICAL TAMPONADES: FOCUS ON PURITY

An extensive range of tamponades for all your procedural needs.

# DID YOU KNOW..

# Why silicone oil tamponade purity is critical?

- Low Molecular Weight Compounds (LMWC) are critical to silicone oil purity<sup>1</sup>
- A statement of LMWC is crucial to understanding silicone oil purity<sup>2</sup>
- Surfactants in silicone oil increase risk of emulsification<sup>1</sup>
- Presence of LMWC and dynamic viscosity differ significant between commercially available silicone oils<sup>1</sup>
- Two-step purification is critical to reducing presence of volatile LMWCs





### Why is purity of DORC silicone oil superior to competition?

- DORC uses a proprietary two-step purification process to reduce LMWC presence to levels lower than most competitors<sup>1</sup>
- DORC silicone oils contain the lowest recorded levels of the potentially harmful M 1000g/mol compounds<sup>1</sup>
- DORC silicone oil specification ensures very low levels of surfactants that can cause emulsification
- DORC provides a certificate of analysis for every batch of silicone oil many competitors fail to provide this critical analysis document
- (1) Comparative Study of Chemical Composition, Molecular and Rheological Properties of Silicone Oil Medical Devices. Raniero Mendichi; Alberto Giacometti Schieroni; Daniele Piovani; Davide Allegrini; Mariantonia Ferrara; Mario R. Romano | https://tinyurl.com/yxr2wzh5
- (2) Januschowski K, Irigoyen C, Pastor JC, et al. Retinal Toxicity of Medical Devices Used during Vitreoretinal Surgery: A Critical Overview. Ophthalmologica. 2018;240(4):236 243. doi:10.1159/000488504 | https://tinyurl.com/y3jtsqal

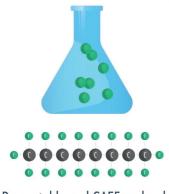
# How to ensure purity of silicone oils?

- Ensure your silicone oil is produced using two-step purification
- Request analysis of LMWC from your silicone oil supplier
- Request a certificate of analysis for every batch of silicone oil used in your hospital showing both LMWC and surfactants

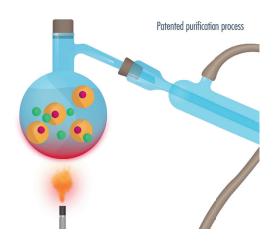
# DID YOU KNOW..

## Why PFCL purity is critical?

- Essential to all medical applications of PFCLs is the control of impurities, especially incompletely fluorinated by-products<sup>1</sup>
- PFCL remains a safe device when concentration of underfluorinated compounds is <10ppm<sup>1</sup>
- Absence of clear regulation of the production, purification and evaluation of the toxic effects of PFCL supposes the possibility that products are not sufficiently safe to obtain CE mark<sup>2</sup>



Pure, stable and SAFE molecule



# How to ensure purity of PFCL?

- Request analysis of impurities from your PFCL supplier – including the level of underfluorinated compounds
- Request information on the level of UV-active substances present in your PFCL
- Request a certificate of analysis for every batch of PFCL oil used in your hospital

# Why is purity of DORC PFCL superior to competition?

- DORC uses a combination of multi-step ultrapurification and analytical characterisationverification to eliminate inherent impurity risks applicable to both Octane and Decalin
- Based on tests of over 40 competitor samples DORC Octane and Decalin has been shown to have amongst the highest levels of purity recorded<sup>3</sup>
- DORC provides a certificate of analysis for every batch of PFCL – many competitors fail to provide this critical analysis document

<sup>(1)</sup> Menz DH, Feltgen N, Menz H, et al. How to Ward Off Retinal Toxicity of Perfluorooctane and Other Perfluorocarbon Liquids?. *Invest Ophthalmol Vis Sci.* 2018;59(12):4841-4846. doi:10.1167/iovs.18-24698

<sup>(2)</sup> Januschowski K, Irigoyen C, Pastor JC, et al. Retinal Toxicity of Medical Devices Used during Vitreoretinal Surgery: A Critical Overview. *Ophthalmologica*. 2018;240(4):236-243. doi:10.1159/000488504

<sup>(3)</sup> Data on file

# DORC offers tamponades for all your procedural needs

#### INTRA-OPERATIVE TAMPONADES

EFTIAR Octane and EFTIAR Decalin liquid is indicated for use as an intraoperative tool for temporary flattening and manipulation of the retina during surgical treatment of retinal detachment, in particular:

- Retinal detachment with giant tears
- Retinal detachment with proliferative vitreoretinopathy
- Traumatic Retinal Detachment
- Luxated Lenses
- Intraocular haemorrhage



#### SHORT OR LONGER TERM TAMPONADE

SIL-1000-S / SIL-2000-S / SIL-5000-S is indicated for use as a short or longer term tamponade of the retina. In particular, the primary indications for SIL-1000-S / SIL-2000-S / SIL-5000-S are the surgical management of:

- Proliferative Vitreoretinopathy (PVR)
- · Retinal Detachment caused by Trauma
- Giant Tears
- Diabetic Traction Detachment.
- All cases of retinal detachment



#### **MID-TERM TAMPONADE**

OcuGas is used as a mid-term tamponade after operative treatment of severe retinal detachment, particularly for:

- Retinal detachments in case of proliferative vitreoretinopathy (PVR) (C2F6 and C3F8 only)
- · Retinal detachments with giant tears
- · Retinal detachments without proliferation
- Retinal detachments in case of proliferative diabetic retinopathy (PDR)
- Traumatic retinal detachments
- Macular holes
- Macular edema



## Intra-operative tamponades: PFCL EFTIAR Octane and Decalin in prefilled syringes

- · Maximized purity.
- 100% fluorinated.
- Chemically inert liquid.
- · Transparent, colorless and optically clear.
- · Low refractive index.
- · High specific gravity.

- · Smooth flattening of a detached retina.
- · Passive drainage of subretinal fluid.

	EFTIAR Octane	EFTIAR Decalin		
Specific gravity	1,77 g/cm³ at 20°C	77 g/cm³ at 20°C 1,93 g/cm³ at 20°C		
Refractive index	1,27 at 20°C	1,31 at 20°C		
Boiling point	101,3-106°C	140,4-142,4°C		
Other		High interfacial tension to silicone oil		
Format	1 syringe, 5ml or 7ml			
Packaging	Box/1, Sterile			
Article number/ name	EFT-OCT5-S EFTIAR Octane 5ml syringe	EFT-DEC5-S EFTIAR Decalin 5ml syringe		
	EFT-OCT7-S EFTIAR Octane 7ml syringe	EFT-DEC7-S EFTIAR Decalin 7ml syringe		



"As surgeons, we need to have the safest possible liquids for our surgeries: ask a producer for a detailed certificate of purification."







© SCHOTT AG, polymer syringe

# EFTIAR PFCL IS SUPPLIED IN HPPS — HIGH PERFORMANCE POLYMER SYRINGES

- SCHOTT TOPPAC® syringe system uses COC material (Cyclo-Olefin-Copolymer)
- EFTIAR PFCL syringe features a cross linked siliconized syringe barrel and Integrated Luer Lock optimum for ease of use.
- Highest quality standards used in production of syringes allow for minimized presence of particles and visual defects and improved drug stability.

#### **Accessories**



Eftiar Dual Bore Cannula (23 gauge / 0.6 mm) Article No: EFD.06



Disposable Dual Bore PFC Cannula Article No: EFD.100



Extendible brush backflush instrument with active aspiration. (23 gauge / 0.6 mm) Article No: 1290.BTD23



**23-gauge soft tipped cannulas** Article No: 1272.SD23



**25-gauge soft tipped cannulas** Article No: 1272.SD25

## Short or longer term tamponades: Silicone Oils 1000cSt/2000cSt/5000cSt in syringes

The D.O.R.C. Silicone oil is a purified silicone oil which allows for a maximum interfacial tension and minimizes interactions between tissues, cells and endo-tamponades media. The physical properties include a combination of specific gravity, refractive index and surface tension. The choice of viscosity offers an optimum balance between easy injection and a stable temporary tamponade.

	1000cSt	2000cSt	5000cSt
Viscosity	1000-1500 mPas	1700-2300 mPas	5000-5900 mPas
Specific Gravity	0,97 g/cm³ at 25°C		
Surface Tension	20 mN/m against air	20 mN/m against air	21 mN/m against air
Interfacial tension	39 mN/m against water	37 mN/m against water	39 mN/m against water
Format	10ml syringe		
Packaging	Box/1, sterile		
Article number/name	SIL-1000-S Silicone Oil, 1.000 csts	SIL-2000-S Silicone Oil, 2.000 csts	SIL-5000-S Silicone Oil, 5.000 csts



"Since D.O.R.C. launched their Silicone oil 2000, I have switched from the 5000 cSt silicone oil to the 2000 cSt. The main reason for switching is the fact that both - injection and extraction - are much easier and faster with the Silicone oil 2000."



Anne-Catherine Gribomont, Prof. MD, Belgium

# Accessories for silicone oil injection



EVA - VFI Pack for Silicone Oil syringes Article No: 1363.DD



Disposable viscous fluid injection / extraction cannula with 7 mm thin wall polyimide tip.(20 gauge / 0.9 mm)

Article No: 1272.VFI20



Disposable VFI Cannula, with 7mm thin wall polyimide tip. (23 gauge / 0.6 mm) Article No: 1272.VFI06



Disposable VFI Cannula, with 7mm thin wall polyimide tip. (25 gauge / 0.5 mm) Article No: 1272.VFI05



Disposable VFI cannula, with 6mm thin wall polyimide tip. (27 gauge / 0.4 mm) Article No: 1272.VFI04



EVA - Universal PVC infusion line for 23G cannula system for VFI/VFE Article No: 1279.VFI

#### Accessories for silicone oil extraction



Disposable pack for viscous fluid extraction. Article No: 1362.D



Disposable Viscous Fluid Extraction cannula with 14 mm thin wall polyimide tip. (20 gauge / 0.9 mm) Article No: 1272.VFE20



EVA - VFI Pack for Silicone Oil syringes Article No: 1363.DD



High Flow Viscous Fluid Extraction. Suitable For 20/23/25/27G DORC Cannula Systems Article No: 1362.VFE



EVA - Universal PVC infusion line for 23G cannula system for VFI/VFE Article No: 1279.VFI



EVA - Heavy Silicone Oil Extraction cannula 23G Article No: 1272.HSE06

### Mid-term tamponades: OcuGas (ready for mixing)

#### Composition and characteristics of OcuGas

OcuGas contains the colorless and odor-less gas which is chemically and physiologically inert. OcuGas is provided as a kit consisting of two sets: a gas reservoir (set 1) and a mixing device (set 2). The complete kit allows an easy, quick and safe handling. Initial purity of Ocugas SF6 is 4.5 Decimal fraction (equal to 99.995% purity), of OcuGas C2F6 - 5.0 Decimal fraction (equal to 99.999 % purity), of OcuGas C3F8 - 4.0 Decimal fraction (equal to 99.999 % purity). OcuGas is used after a complete vitrectomy.



	SF6	C2F6	C3F8
CAS number	2551-62-4	76-16-4	76-19-7
Density	(20°C, 1 bar) 6,07 kg/m <sup>3</sup>	(15°C, 1 bar) 5.84 kg/m <sup>3</sup>	Density (15°C, 1 bar) 8.17 kg/m <sup>3</sup>
Density ratio to air	5,1	4,8	6,5
Duration	up to 2 weeks	up to 5 weeks	up to 8 weeks
Packaging	Box/1		
Article number/ name	GAS-SF6-S OcuGas SF6	GAS-C2F6-S OcuGas C2F6	GAS-C3F8-S OcuGas C3F8

### **Backflush Instruments**

23G

Backflush Instrument with 23 gauge / 0.6mm





Blunt needle Article No: 2281.AD06



Brush needle and active aspiration Article No: 2281.BTD06



Soft-tip cannula and active aspiration Article No: 2281.STD06

25G

Backflush Instrument with 25 gauge / 0.5mm





Blunt needle and active aspiration Article No: 2281.AD05



Brush needle and active aspiration Article No: 2281.BTD05



Soft-tip cannula and active aspiration Article No: 2281.STD05

Backflush Instrument with 27 gauge / 0.4mm





Blunt needle and active aspiration Article No: 2281.AD04



Brush needle and active aspiration Article No: 2281.BTD04



Soft-tip cannula and active aspiration Article No: 2281.STD04

Backflush Instrument with 20 gauge / 0.9mm





Blunt needle Article No: 2281.AD



Brush needle and active aspiration Article No: 2281.BTD



For additional information please contact: D.O.R.C. Dutch Ophthalmic Research Center (International) B.V. Scheijdelveweg 2, 3214 VN Zuidland, The Netherlands

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