

Bausch & Lomb

# Vitreoretinal Tamponades

Dk-line<sup>®</sup>, Okta-line<sup>®</sup>, Oxane<sup>®</sup>, Oxane Hd<sup>®</sup>



**Incomparable Purity**



Perfluorocarbon Liquids, Silicone Oil,  
Heavier than water endotamponade

*Dk-line® was the first available, 100% fluorinated, purified perfluorodecalin. With the introduction of Okta-line®, Bausch & Lomb now offers vitreoretinal surgeons two excellent intra-operative tools for use in treatment of retinal disorders. Dk-line® and Okta-line® offer reduced surgical time and improved outcomes.*

# Perfluorocarbon Liquids: the worldw



**Dk-line®**  
C<sub>10</sub>F<sub>18</sub> Perfluorodecaline



**Okta-line®**  
C<sub>8</sub>F<sub>18</sub> Perfluoro-n-octane



## Excellent visibility

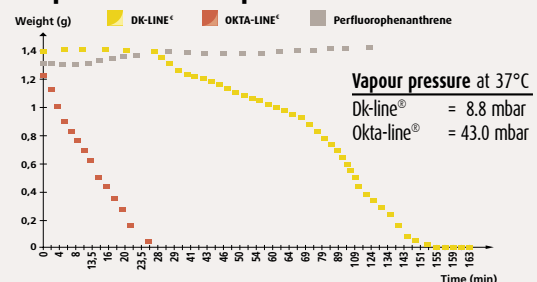
**PFCL bubble in the presence of an intraocular irrigating solution (Aqsia®)**



Refractive index at 20°C	
Dk-line®	= 1.31
Okta-line®	= 1.27
Perfluorophenanthrene	= 1.33
Aqsia®	= 1.33

## Spontaneous evaporation

**Elimination of residual drops by spontaneous evaporation of the product**



(1) «Perfluorocarbon liquid in the management of retinal detachment with proliferative vitreoretinopathy.» GE Coll, S Chang, J Sun - Ophthalmology, 1995, Vol 102, N° 4. (2) «Résultats anatomiques comparés à long terme de décollements de rétine avec la prolifération vitréo-rétinienne opérés avec ou sans utilisation de perfluorocarbones liquides.» F Béhar Cohen, JF Le Roule, D Chauvaud - J. Fr. Ophthalmology, 1999; 22, 8, 853-858. (3) «Intérêt des perfluorocarbones liquides dans la prévention de la prolifération vitréo-rétinienne après déchirure géante avec inversion rétinienne.» D Chauvaud, G Caputo, L Werner - Bordeaux Symposium International of Ophthalmology, Sept 1993. (4) «Use of perfluorocarbon liquids in proliferative vitreoretinopathy: results and complications» U. Stolba, S. Binder, M. Velikay - British Journal of Ophthalmology 1995, 79: 1106-1110. (5) «Experimental long-term vitreous replacement with purified and non-purified perfluorodecalin.» M. Velikay and Al. - Am. J. Of Ophthalmology 116, 563-570, Nov. 1993.

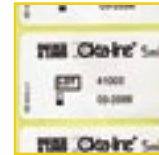
AVAILABLE



<b>VRL100</b>	STERILE	CE0125	<b>DK-line® 5ml</b>
<b>VRL110</b>	STERILE	CE0125	<b>DK-line® 7ml</b>
<b>VRL200</b>	STERILE	CE0125	<b>Okta-line® 5ml</b>

**Precautions:**

- Perfluorocarbon liquids must be removed at the end of the procedure.
- PFCLs are delivered with one 5ml or 10ml plastic syringe and one 20 gauge cannula. The vial stopper must be removed before drawing up the PFCL. The same cannula can be used intraocularly only if it has not been in contact with the vial stopper.



All Bausch & Lomb products are delivered with 4 patients' records labels for ultimate traceability.

# Wide reference

## Indications

■ Retinal detachment (RD) with giant tears

■ RD complicated by PVR

■ Proliferative diabetic retinopathy

■ Macular holes with peripheral RD

■ Endophotocoagulation under PFCL

■ Retrieval of foreign bodies from vitreous

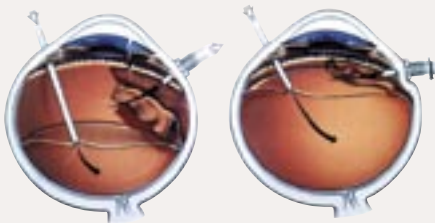
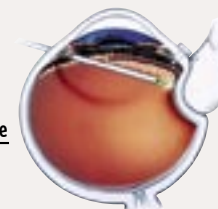


Photo Prof. A. Mathis

The density of PFCL perfectly stabilises the retina after vitrectomy and resection of epiretinal membranes, PFCL injection enables spontaneous and total retinal reattachment

**Specific Gravity at 25°C**  
 Dk-line® = 1.93  
 Okta-line® = 1.77

**Boiling Temperature**  
 Dk-line® = 141°  
 Okta-line® = 104°



The resistance of PFCL to high temperature improves the quality of endophotocoagulation.



After vitrectomy, PFCL injection returns the crystalline lens to the anterior segment, without traumatising the tissue.

## Proved efficiency

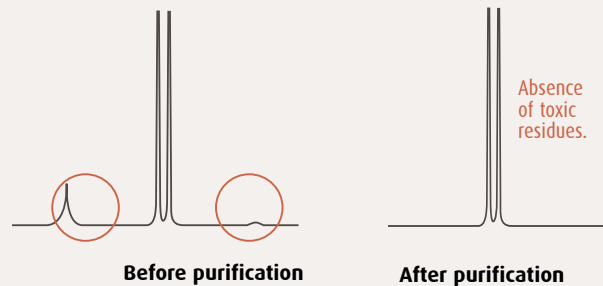
Over 90% of patients had a reattached retina after 6 months, with Dk-line® (2)

	Manual reapplication	Reapplication with Dk-line®
	Silicone oil	Silicone oil
Success of retinal reapplication	80 %	100 %
Incidence of post-operative PVR	83 %	31 %
Average delay of onset	= 2.5 months	= 5.25 months
Retina reattached at 6 months	40 %	94 %

## Inert and Pure

Tolerance studies have widely demonstrated the importance of purification in ocular endotamponade(5).

**Gas chromatographic analysis**



*Oxane® 1300 and Oxane® 5700 silicone oils are highly purified and provide a prolonged endotamponade of constant volume.*

# Silicone Oil : the highest degree of p



**Oxane®**  
Polydimethylsiloxane 1300



**Oxane®**  
Polydimethylsiloxane 5700

## Clearly superior

## Highly Purified<sup>(1)</sup>

Common purification silicone oil process in the presence of an irrigating solution (Aqsia®).

**Aqsia**

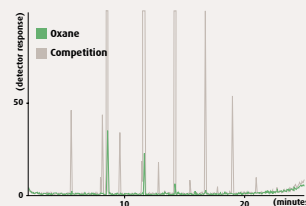
Common purification silicone oil process

**Refractive index at 20°C**  
Aqsia® = 1.33  
Oxane® = 1.40

**Aqsia**

Oxane® in the presence of an irrigating solution (Aqsia®).

### Gas chromatography / Mass spectroscopy



**Oligosiloxanes up to 5 Si atoms**  
Oxane®  
Sum: < 3ppm  
Competition  
Sum: 230ppm

(1) «Clinical consequences of the use of highly purified silicone oil» JC Pastor, JM Zarco, MJ Del Nozal - European Journal of Ophthalmology, Vol 8, N°3, 1998 (2) "Silicone Oil in Treatment of Complicated Retinal Detachments", K Lucke, H Laqua - Springer-Verlag, 1990. (3) "Giant retinal tears. Surgical techniques and results using Perfluorodecalin and Silicone Oil tamponade" A Mathis, V Pagot, C Gazagne, F Maleceze - Retina, Vol 12, Number 3S, 1992. (4) "Analysis and fractionation of silicone and fluorosilicone oils for intraocular use" Nakamura K, Refojo MF, Crabtree DV, Leong FL Invest Ophthalmol Vis Sci 1990 Oct;31(10): 2059-2069

AVAILABLE



VRL500

STERILE



CE0125

Oxane® 1300, 10ml Syringe

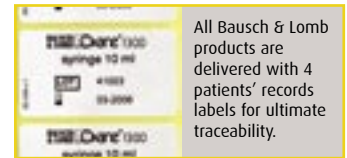
VRL600

STERILE



CE0125

Oxane® 5700, 10ml Syringe



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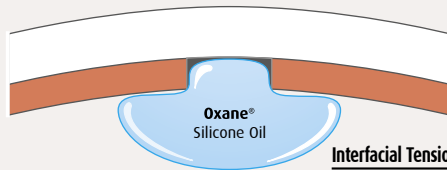
urity

## Indications

- PVR C state
- Giant tears with PVR
- PDR
- RD by perforating trauma
- Intra-operative intra-vitreous haemorrhage
- Epiretinal membranes

## High Interfacial Tension

Oxane®'s high interfacial tension allows formation of an intraocular layer non miscible with other fluid; Oxane® provides good coverage, even if the retina is irregular or when there is a dehiscence.



**Interfacial Tension** (vs water)  
 Oxane® 1300 = 44.9 mN-m  
 Oxane® 5700 = 44.9 mN-m

## PFCL/Silicone Oil exchange

PFCL is removed by maintaining the aspiration cannula tip just under the interface between the PFCL and silicone oil.



Photo Prof. A. Mathis

## Injection

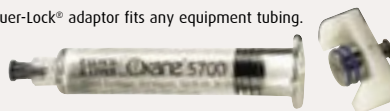
### Automatic injection with Millennium™ Microsurgical System

**CX5720** Viscous Fluid Pack for Silicone Oil syringe (Packaged 6 per box)  
 STERILE



### Automatic injection with other equipment

**99902** Reusable Silicone Oil Syringe Adaptor  
 This Luer-Lock® adaptor fits any equipment tubing.



### Manual injection

**99903** Reusable holding device for Silicone Oil Syringe



## Aspiration

### Automatic aspiration with Millennium™ Microsurgical system

**CX5710** Viscous Fluid Pack (Packaged 6 per box)  
 STERILE



Oxane® Hd is an exclusive mixture of ultra-purified silicone oil and RMN3 (patented partially fluorinated olefin).

# Exclusive heavier than water, long t



## Properties

	Oxane® 1300 or Oxane® 5700	Oxane® Hd	Clinical Benefits
<b>Density</b> (at 22°C)	0.98 g/cm <sup>3</sup>	1.02 g/cm <sup>3</sup>	■ Heavier than water endotamponade allows effective tamponade of inferior and posterior breaks
<b>Viscosity</b> (at 25°C)	1000 or 5000 mPa.s	3300 mPa.s	■ Medium range viscosity allows easy automatic injection
<b>Interfacial Tension/ Irrigating solution</b>	> 40 mN.m	> 40 mN.m	■ Like standard Silicone Oil, its interfacial tension allows intraocular tamponade: formation of a sole intraocular bubble, prevents fluids passage through retinal breaks allowing progressive reattachment.
<b>Refractive index</b> (at 20°C)	1.40	1.40	■ Distinguishable refractive index compared to irrigating solution and PFCL favouring excellent visibility during injection/aspiration.

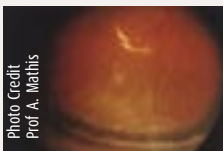


Photo Credit Prof. A. Mathis

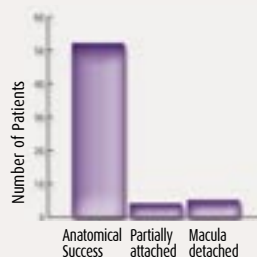
### Patients Benefits

- More comfort because postoperative face down positioning is not required
- Allows for more aesthetic 12 o'clock iridectomy
- Avoids passage of Silicone Oil in the anterior chamber in phakic or pseudophakic eyes
- Potentially diminished risk of postoperative anterior and inferior re proliferation

## Clinical Experience

<b>Purpose</b>	To evaluate performance and safety of Oxane® Hd
<b>Inclusion Criteria</b>	RD complicated by posterior PVR stage > = C2, anterior PVR, giants retinal tears, penetrating trauma
<b>Follow Up</b>	1, 3, 6 months and 1 year
<b>Number of patients</b>	33 eyes in Germany, 30 eyes in France
<b>Investigators team</b>	FRANCE: Prof. Mathis, Dr. Pagot-Mathis, Prof. Chauvaud, Dr. Morel, Dr. Monin, Dr. Larricart, Dr. Le Rouic GERMANY: Prof. Wolf

85% of Anatomical Success






Encouraging Functional Results


Postoperative visual acuity	Results
>=20/400	73%

### Publications and Lectures


- "Silicone oil - RMN3 Mixture ("Heavy silicone oil") as an internal tamponade for complicated retinal detachment." Wolf S. / RETINA 2003 (to be published).
- "Management of complicated retinal detachment using a new heavy silicone oil as temporary internal tamponade: final results." Mathis A. / XXIII Club Jules Gonin Montreux, 2002
- "Efficacité et tolérance d'une nouvelle huile de silicone lourde en chirurgie vitréorétinienne: résultats définitifs." Mathis A. / SFO Paris, 2002.
- "A prospective study on heavy silicone oil as an internal tamponade for complicated retinal detachment." Wolf S. / WAO Sydney, 2002
- "Management of complicated retinal detachment using a new heavy silicone oil as temporary internal tamponade." Morel C. / ARVO Fort Lauderdale, 2001
- "Heavy silicone oil as internal tamponade for complicated retinal detachment." Wolf S. / ARVO Fort Lauderdale, 2001
- "Heavy silicone oil as internal tamponade for complicated retinal detachment." Wolf S. / XXII Club Jules Gonin Taormina, 2000
- "Management of complicated retinal detachment using a new heavy silicone oil as temporary internal tamponade." Mathis A. / XXII Club Jules Gonin Taormina, 2000

**AVAILABLE** 

**VRL700** **STERILE**   **Oxane® Hd 10ml Syringe**

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**Storage Instruction**

 +15°C  
+59°F

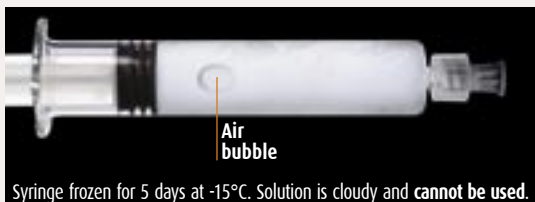
# erm endotamponade

## Indications

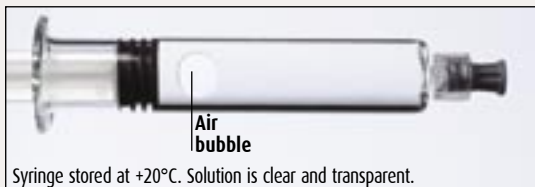
- Inferior and posterior retinal breaks
- RD complicated by severe PVR, penetrating trauma, giant tears
- Inferior retinectomy for anterior PVR

## Storage Precautions

Like other liquids used in ophthalmology careful handling of the product is required. Oxane® Hd may separate if stored at temperature lower than +15°C (+59°F). *The use of Oxane® Hd which has separated may affect the safety and performance of the product.*



**Prior to use, visually inspect the substance to confirm that it is clear and transparent. Do not use if the substance appears cloudy or if there is any other indication that the liquid substance has separated.**



**Oxane® Hd which has separated may remix if stored for a minimum period of 72 hours at ambient temperature of 20°C / 68°F. When using Oxane® Hd which has been stored in this fraction, the substance must again be visually inspected before use and all directions for use and warnings set forth herein must be followed.**

## Injection

## Aspiration

### Automatic injection with Millennium™ Microsurgical System

**CX5720** Viscous Fluid Pack for Silicone Oil syringe (Packaged 6 per box)  
**STERILE**  



### Automatic injection with other equipment

**99902** Reusable Silicone Oil Syringe Adaptor  
This Luer-Lock® adaptor fits any equipment tubing.



### Manual injection

**99903** Reusable holding device for Silicone Oil Syringe



### Automatic aspiration with Millennium™ Microsurgical System

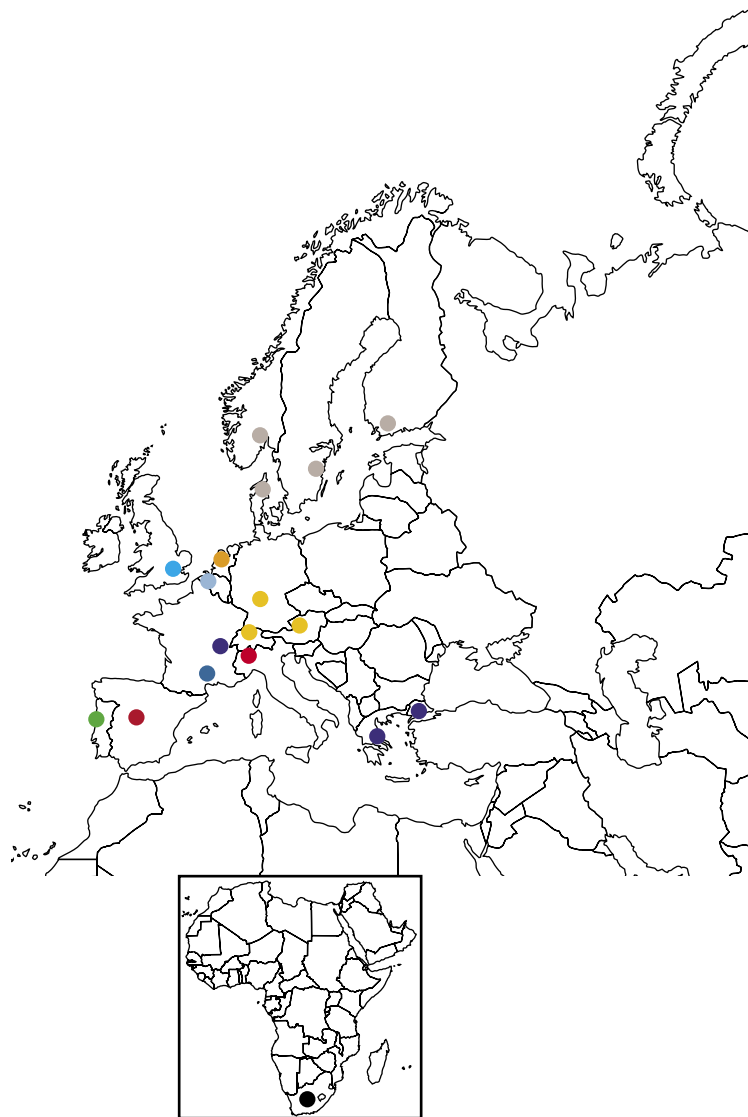
**CX5710** Viscous Fluid Pack (Packaged 6 per box)  
**STERILE**  



### Manual Aspiration

The use of active aspiration using 19 or 20 gauge extrusion cannula (1.5mm-2mm long) is required.

# Bausch & Lomb



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