

Bausch & Lomb

Vitreoretinal Tamponades

Dk-line[®], Okta-line[®], Oxane[®], Oxane Hd[®]



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®
C₁₀F₁₈ Perfluorodecaline



Okta-line®
C₈F₁₈ Perfluoro-n-octane



Excellent visibility

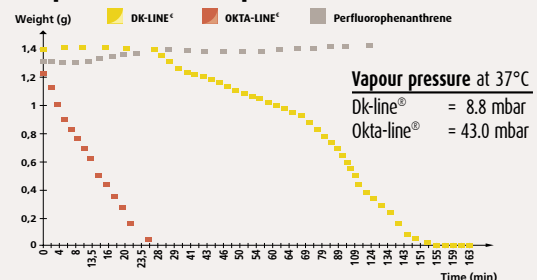
PFCL bubble in the presence of an intraocular irrigating solution (Aqsia®)



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



VRL100	STERILE	CE0125	DK-line® 5ml
VRL110	STERILE	CE0125	DK-line® 7ml
VRL200	STERILE	CE0125	Okta-line® 5ml

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

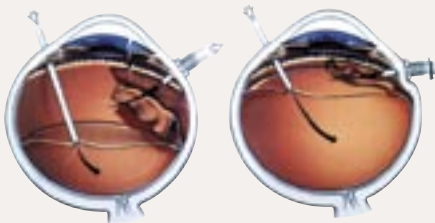


Photo Prof. A. Mathis

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.

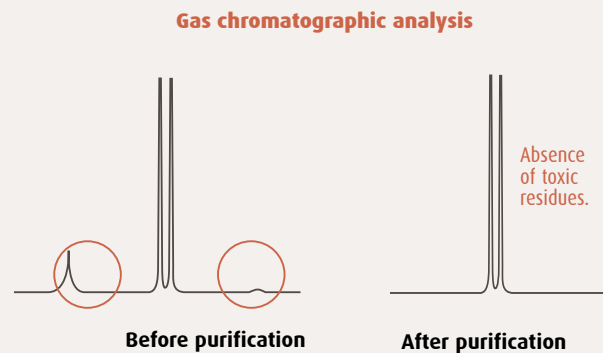
Proved efficiency

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).



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⁽¹⁾

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

Aqsia®

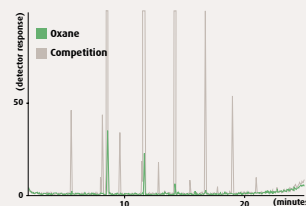
Common purification silicone oil process

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

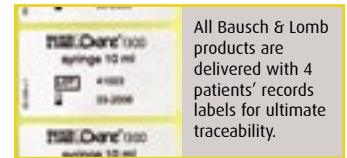
(1) «Clinical consequences of the use of highly purified silicone oil» JC Pastor, JM Zarco, MJ Del Nozal - European Journal of Ophthalmology, Vol 8, N°3, 1998 (2) "Silicone Oil in Treatment of Complicated Retinal Detachments", K Lucke, H Laqua - Springer-Verlag, 1990. (3) "Giant retinal tears. Surgical 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 \otimes CE0125 Oxane® 1300, 10ml Syringe

VRL600 STERILE \otimes CE0125 Oxane® 5700, 10ml Syringe



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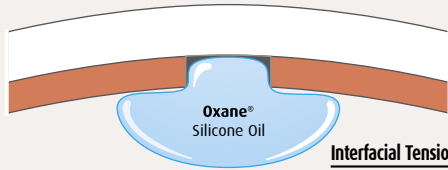
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Indications

- 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.

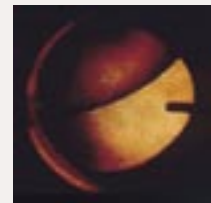


Photo Prof. A. Mathis

Injection

Automatic injection with Millennium™ Microsurgical System

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



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 \otimes



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

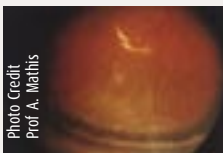
Exclusive heavier than water, long t



Properties

	Oxane® 1300 or Oxane® 5700	Oxane® Hd	Clinical Benefits
Density (at 22°C)	0.98 g/cm ³	1.02 g/cm ³	■ Heavier than water endotamponade allows effective tamponade of inferior and posterior breaks
Viscosity (at 25°C)	1000 or 5000 mPa.s	3300 mPa.s	■ Medium range viscosity allows easy automatic injection
Interfacial Tension/ Irrigating solution	> 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.
Refractive index (at 20°C)	1.40	1.40	■ Distinguishable refractive index compared to irrigating solution and PFCL favouring excellent visibility during injection/aspiration.

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


Purpose	To evaluate performance and safety of Oxane® Hd	<div style="background-color: #4a4a8a; color: white; padding: 5px; text-align: center;">85% of Anatomical Success</div>	<div style="background-color: #4a4a8a; color: white; padding: 5px; text-align: center;">Encouraging Functional Results</div>				
Inclusion Criteria	RD complicated by posterior PVR stage > = C2, anterior PVR, giants retinal tears, penetrating trauma						
Follow Up	1, 3, 6 months and 1 year		<table border="1" style="width: 100%;"> <thead> <tr> <th>Postoperative visual acuity</th> <th>Results</th> </tr> </thead> <tbody> <tr> <td>>=20/400</td> <td>73%</td> </tr> </tbody> </table>	Postoperative visual acuity	Results	>=20/400	73%
Postoperative visual acuity	Results						
>=20/400	73%						
Number of patients	33 eyes in Germany, 30 eyes in France						
Investigators team	FRANCE: Prof. Mathis, Dr. Pagot-Mathis, Prof. Chauvaud, Dr. Morel, Dr. Monin, Dr. Larricart, Dr. Le Rouic GERMANY: Prof. Wolf						

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

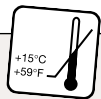
erm endotamponade

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.*



Syringe frozen for 5 days at -15°C. Solution is cloudy and cannot be used.



Syringe stored for 5 days at +5°C. Solution is separated and cannot be used.

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.



Syringe stored at +20°C. Solution is clear and transparent.



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

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

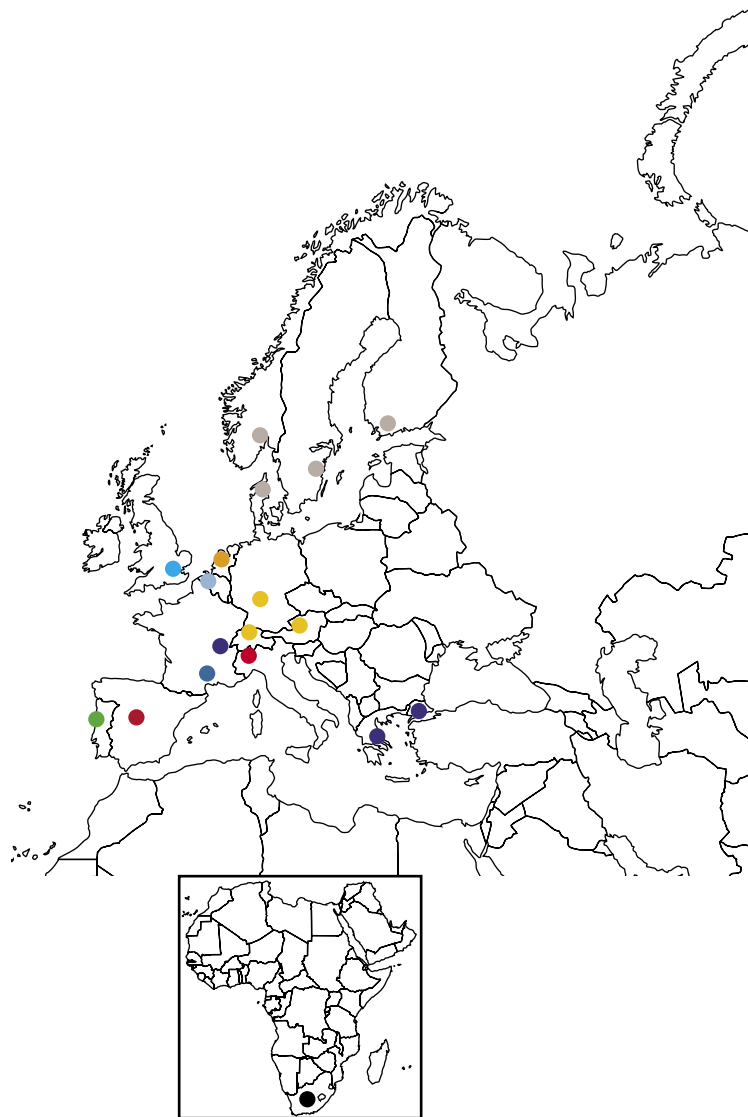
Automatic aspiration with Millennium™ Microsurgical System

CX5710 Viscous Fluid Pack (Packaged 6 per box)
STERILE  



Manual Aspiration

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



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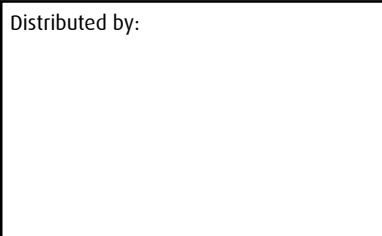
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