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
**Perfluorocarbon Liquids**

**Proved efficiency**

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

<table>
<thead>
<tr>
<th>Manual reapplication</th>
<th>Replication with Dk-line®</th>
</tr>
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<tbody>
<tr>
<td>Silicone oil</td>
<td>Silicone oil</td>
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<tr>
<th>Success of retinal reattachment</th>
<th>80 %</th>
<th>100 %</th>
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<tbody>
<tr>
<td>Incidence of post-operative PVR</td>
<td>83 %</td>
<td>31 %</td>
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</table>

**Inert and Pure**

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

**Gas chromatographic analysis**

- Absence of toxic residues.

**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 intracocularly only if it has not been in contact with the vial stopper.

**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

**Specific Gravity**

- Dk-line® at 25°C: 1.93
- Okta-line®: 1.77

**Boiling Temperature**

- Dk-line®: 141°
- Okta-line®: 104°

**Precautions:**

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- 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 intracocularly only if it has not been in contact with the vial stopper.
Oxane® 1300 and Oxane® 5700 silicone oils are highly purified and provide a prolonged endotamponade of constant volume.

Silicone Oil: the highest degree of purity

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

RefRACTIVE INDEX

Aqsia® = 1.33
Oxane® = 1.40

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

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

Gas chromatography / Mass spectroscopy

Silicone Oil: the highest degree of purity

**Indications**
- PVR C state
- Giant tears with PVR
- PDR
- RD by perforating trauma
- Intra-operative intra-vitreal 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.

**PFCL/Silicone Oil exchange**
PFCL is removed by maintaining the aspiration cannula tip just under the interface between the PFCL and silicone oil.

**Injection**
- Automatic injection with Millennium™ Microsurgical System
  - CX5720: Viscous Fluid Pack for Silicone Oil syringe (Packaged 6 per box)
- Automatic injection with other equipment
  - 99902: Reusable Silicone Oil Syringe Adaptor
  - Manual injection
    - 99903: Reusable holding device for Silicone Oil Syringe

**Aspiration**
- Automatic aspiration with Millennium™ Microsurgical system
  - CK5710: Viscous Fluid Pack (Packaged 6 per box)
Oxane® Hd is an exclusive mixture of ultra-purified silicone oil and RMN3 (patented partially fluorinated olefin).

**Properties**

<table>
<thead>
<tr>
<th></th>
<th>Oxane® 1300 or Oxane® 5700</th>
<th>Oxane® Hd</th>
<th>Clinical Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Density (at 22°C)</td>
<td>0.98 g/cm³</td>
<td>1.02 g/cm³</td>
<td>Heavier than water endotamponade allows effective tamponade of inferior and posterior breaks.</td>
</tr>
<tr>
<td>Viscosity (at 25°C)</td>
<td>1000 or 5000 mPa.s</td>
<td>3300 mPa.s</td>
<td>Medium range viscosity allows easy automatic injection.</td>
</tr>
<tr>
<td>Interfacial Tension/</td>
<td>&gt; 40 mN/m</td>
<td>&gt; 40 mN/m</td>
<td>Like standard Silicone Oil, its interfacial tension allows intracocular tamponade: formation of a sole intraocular bubble, prevents fluids passage through retinal breaks allowing progressive reattachment.</td>
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<tr>
<td>Irrigating solution</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refractive index</td>
<td>1.40</td>
<td>1.40</td>
<td>Distinguishable refractive index compared to irrigating solution and PFCL favouring excellent visibility during injection/aspiration.</td>
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**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 reproliferation.

**Clinical Experience**

**Purpose**
To evaluate performance and safety of Oxane® Hd

**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

**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

**85% of Anatomical Success**

<table>
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<tr>
<th>Postoperative visual acuity</th>
<th>Results</th>
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<tr>
<td>&gt;=20/400</td>
<td>73%</td>
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**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).
**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**

**Automatic injection with Millennium™ Microsurgical System**

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

**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)

**Manual Aspiration**

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