Silicone Oil

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**Manufactured:**
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Silicone Oil SmartSil 1000, SmartSil 5000

SmartSil 1000  SmartSil 5000

CE Marked 02 March 2012

10.0 ml oil in syringe 20 ml

www.rumex.net
What is silicone oil?

Liquid which is designed for retinal endotamponade after vitrectomy

Polymer of POLYDIMETHYLSILOXANE

\[
\text{-[-]-[-]} \quad \text{Dimethyl 4} \\
\text{-[-]-[-]-[-]} \quad \text{Dimethyl 5} \\
\text{-[-]-[-]-[-]-[-]} \quad \text{Dimethyl n}
\]

Characteristics

- Transparency
- High refractive index (1.4)
- Low density (0.96±0.02)
- High interface tension
- Not toxic long polymers

Benefits

- Excellent visualization of the posterior segment
- Does not interfere with laser coagulation of the retina (laser calibration for refractive index 1.4)
- Prolonged tamponade
- High biocompatibility
- Easy injection and removal from the eye
Emulsification of the silicone oil

Silicone oil = heteropolymer of DIMETHYLSILOXANE
± long molecular chains with medium chains

\[(\text{CH}_3)_3 - [\text{(CH}_3)_2\text{Si-O}]_n - (\text{CH}_3)_3\]

- [-] [-] [-] [-] Dimethyl 4
- [-] [-] [-] [-] Dimethyl 5
- [-] [-] [-] [-] [-] [-] [-] Dimethyl \( n \)

D 2 - D 20 = Oligomers

Emulsification – increase of content of low molecular weight compounds

Rumex is used only ultra purified silicone oils with long molecular chain compounds (fractionating) in order to prevent emulsification (D2 - D20)
Emulsification

Emulsified silicone oil

Not emulsified silicone oil
The composition of the silicone oil

- **Technical Oil**
  - Molecules with different chains length and weight including foreign substances and oligomers

- **Purified medicinal oil (Other manufacturers)**
  - Molecules with different chains length and weight without foreign substances and oligomers

- **Fractionated oil (Rumex)**
  - Separation of molecules with different chains length and weight. *Rumex oil* has only molecules with long chains length ↔ *not emulsification*

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*SmartSil*
Silicone Oil SmartSil 1000/5000

SmartSil 1000/5000 is an ultra purified silicone oil which leads to maximum interactions between tissues, cells and endotamponades 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.
SmartSil 1000/5000 is designed for the retinal endotamponade after vitrectomy.
SmartSil 1000, SmartSil 5000

Appearance: viscous, transparent, odorless liquid
Formula: 

POLYDIMETHYLSILOXANE

\[
\begin{array}{c}
\text{H}_3\text{C} - \text{Si} - \text{O} \quad \text{Si} - \text{O} \quad \text{Si} - \text{CH}_3 \\
\text{CH}_3 \quad \text{CH}_3 \quad \text{CH}_3 \quad \text{CH}_3 \\
\end{array}
\]

\[n\]
Exclusive Purification

Vacuum molecular distillation purification of the RUMEX Int. LTD. Silicone oil:
* Solvent free purification
* Potentially toxic low molecular weight oligomers (D_4 to D_20) extraction
* Residual volatile components extraction (water, ethanol, …)

Post-purification controls:
* Gel permeation chromatography (GPC)
* Gaseous chromatography (GC)
Emulsification

Implantation time
There is no recommend implantation time for the silicone oil.
The implantation duration must be controlled and adapted to the retinal state of the patient.

Emulsification
Rumex silicone oil has proven an excellent stability and optimal transparency because of its exclusive vacuum molecular distillation purification. No solvent are used, potentially toxic low molecular weight and residual volatile components (water, ethanol) that could lead to emulsification are extracted in the purification process.
Purification process

PURIFICATION PROCESS:

Because the silicone oil replaces the vitreous, it must be clear and transparent in order to let both the patient and the surgeons see through it. One of the main risk after injecting silicone oil is to see it becoming opaque because of an emulsification process. In order to avoid any emulsification risk, the purification process is a key element for the manufacture of a safe and reliable silicone oil.

This is why Rumex silicone oil purification process is unique: it is called vacuum molecular distillation purification. The purification process aims to get rid of the low molecular weight oligomers which might cause an emulsification. Usually, our competitors are adding some solvents like ethanol in order to remove the low molecular weight oligomers. After, they rinse the solvent with water in order to remove it from the silicone oil. While doing this, they take a double risk: the first risk is to leave some solvent in the silicone oil, which is very toxic. The second risk is to leave some water in the silicone oil: water might cause emulsification of the oil. The Rumex vacuum molecular distillation purification process does not use any water or solvent; in fact this process removes the low molecular weight oligomers without adding any substance to the silicone oil. This is why we think our silicone oil is one of the purest available on the market.

No emulsification shall occur when doctor will use the recommendation mentioned in the instructions for use.
Purification
Indications

SMARTSIL is indicated in prolonged tamponade after surgical treatment for severe retinal detachment, especially:

- retinal detachment with proliferative vitreoretinopathy
- retinal detachment that complicate a diabetic retinopathy
- retinal detachment with giant tears
- traumatic retinal detachment
- secondary retinal detachment to a viral retinitis
Packaging

SMARTSIL is supplied sterile. It is dry heat sterilized in its primary packaging (syringe). This is then packaged in a pouch for a steam sterilization, to make it easier to handle in aseptic conditions. Our purification process guarantees a pure silicone oil, free of low molecular weight components and synthesis residues. SMARTSIL is a single-use liquid and must not be resterilized.
Complete set

* High resistant glass syringe 20 ml with silicone oil 10 ml
* Silicone plunger
  +
* Reusable/disposable tubing for syringe.
  Vitrectomy system: Assistant®, Pentasys®, Harmony Buget®, Associate®, Constellation®, Accurus®, Millenium®, Stellaris®, Orbit®
  +
* Viscous Fluid Injection Cannula, 23G or 25G, 10 mm polyimide tip
### Physico-chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interfacial tension</td>
<td>43.2 mN m^(-1) at 37°C</td>
</tr>
<tr>
<td>Density</td>
<td>0.97 g/cm³</td>
</tr>
<tr>
<td>Viscosity</td>
<td>1000 cSt, 5000 cSt</td>
</tr>
<tr>
<td>Refractive index</td>
<td>1.404</td>
</tr>
<tr>
<td>Volatility</td>
<td>0.06%</td>
</tr>
<tr>
<td>Polydispersity</td>
<td>2.33</td>
</tr>
<tr>
<td>Elements potentially toxic</td>
<td>&lt; 3 ppm</td>
</tr>
<tr>
<td>Low molecular weights</td>
<td>D4 - D9: ≤ 24 ppm</td>
</tr>
<tr>
<td></td>
<td>D10 - D20: ≤ 4 ppm</td>
</tr>
<tr>
<td>Volume of oil</td>
<td>10 ml</td>
</tr>
<tr>
<td>Syringe</td>
<td>20 ml</td>
</tr>
</tbody>
</table>
## Competitors

<table>
<thead>
<tr>
<th>Company</th>
<th>Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Baush &amp; Lomb, USA</td>
<td>Oxane 1300®, Oxane 5700®</td>
</tr>
<tr>
<td>b. DORC, the Netherlands</td>
<td>Sil-1000®, Sil-5000®</td>
</tr>
<tr>
<td>c. Acri.Tec GmbH, Germany</td>
<td>Acri.Sil-ol 1000, Acri.Sil-ol 5000</td>
</tr>
<tr>
<td>d. Micromed, Italy</td>
<td>PDMS 1000, PDMS 2000, PDMS 5000</td>
</tr>
<tr>
<td>e. Alcon, USA</td>
<td>Silicone™ 1000</td>
</tr>
<tr>
<td>f. Alchimia, Italy</td>
<td>RS-OIL ECS 1000/5000</td>
</tr>
<tr>
<td>g. Geuder, Germany</td>
<td>Siluron 1000/2000/5000</td>
</tr>
<tr>
<td>h. Arcad, France</td>
<td>Acriolane® 1300/5500</td>
</tr>
<tr>
<td>i. Aurolab, India</td>
<td>Aurosil® 1000/5000</td>
</tr>
<tr>
<td>j. Alamedics, Germany</td>
<td>Ala®sil 1000/5000</td>
</tr>
<tr>
<td>k. Biotech, India</td>
<td>BioSil® 1000/5000</td>
</tr>
<tr>
<td>l. Croma Pharma, Austria</td>
<td>Vitreocrom® 1000/5000</td>
</tr>
</tbody>
</table>
Interface tension

Indicates the capacity for the silicone oil to form a bubble

<table>
<thead>
<tr>
<th></th>
<th>Rumex</th>
<th>AcriTec</th>
<th>Micromed</th>
<th>B&amp;L</th>
<th>DORC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interface tension, mN m^(-1)</td>
<td>43.2</td>
<td>42.7</td>
<td>42.7</td>
<td>40</td>
<td>21</td>
</tr>
</tbody>
</table>

-> Rumex has the highest interface tension of the silicone oils analysed!
Polydispersity

Indicates the repartition of the molecular chains of various sizes. A perfect polymer would have an index of one (1). It would indicate that all molecular chains have exactly the same lengths, that is a perfect homogeneity.

<table>
<thead>
<tr>
<th></th>
<th>Rumex</th>
<th>AcriTec</th>
<th>Micromed</th>
<th>B&amp;L</th>
<th>Aurolab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polydispersity</td>
<td>2.33</td>
<td>2.35</td>
<td>2.34</td>
<td>2.30</td>
<td>2.50</td>
</tr>
</tbody>
</table>

-> Rumex has one of the lowest index. In our oil, the majority of the chains are medium, with only few small and large chains!
### Elements potentially toxic

Indicates the concentration of toxic elements such as Cr, Co, Ni, Zn, Cd, Sn, Sb, Pb, etc.

<table>
<thead>
<tr>
<th></th>
<th>Rumex</th>
<th>AcriTec</th>
<th>Micromed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elements potentially toxic (ppm)</td>
<td>&lt; 3</td>
<td>&lt; 4</td>
<td>&lt; 4</td>
</tr>
</tbody>
</table>

-> Rumex has the lowest value!
Refractive index

It gives an indication of how the light reflects at the contact of the material. The air has an index close from one (1). It means that light is not reflecting in the air.

<table>
<thead>
<tr>
<th></th>
<th>Rumex</th>
<th>AcriTec</th>
<th>Micromed</th>
<th>B&amp;L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refractive index</td>
<td>1.404</td>
<td>1.403</td>
<td>1.404</td>
<td>1.400</td>
</tr>
</tbody>
</table>

-> The indexes are very similar!
Volatility

It indicates the capacity of vaporization of the silicone oil in the atmosphere. For example, paint has a very high volatility. A low volatility index indicates a high stability of the oil.

<table>
<thead>
<tr>
<th></th>
<th>Rumex</th>
<th>AcriTec</th>
<th>Micromed</th>
<th>Alamedics</th>
<th>Geuder</th>
<th>Arcad</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volatility, %</td>
<td>0.06</td>
<td>0.05</td>
<td>0.15</td>
<td>0.10</td>
<td>0.15</td>
<td>0.10</td>
</tr>
</tbody>
</table>

-> Micromed and Geuder volatility is very high!
Low molecular weights

The measures below indicate the concentration of oligomers that contain between 4 and 20 molecules. These short molecular chains have to be eliminated with a purification process. If they are not removed, they can:

- Migrate in the tissues
- Migrate in the anterior chamber
- Close themselves in buckles, creating toxic oligomers
- Increase the risks of emulsification of the oil

<table>
<thead>
<tr>
<th>Number of molecular chains</th>
<th>Rumex</th>
<th>AcriTec</th>
<th>Micromed</th>
<th>Aurolab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low molecular weights</td>
<td>D4 to D9</td>
<td>24</td>
<td>77</td>
<td>261</td>
</tr>
<tr>
<td></td>
<td>D10 to D20</td>
<td>4</td>
<td>408</td>
<td>842</td>
</tr>
</tbody>
</table>

AcriTec, Micromed and Aurolab have a very high values!
Viscosity

There is no relation between viscosity and interface tension. For example, B&L and Arcad has an interface tension exactly the same as Rumex, but is more viscous. It is more difficult to inject, even if it does not maintain better the retina in position.

<table>
<thead>
<tr>
<th></th>
<th>Viscosity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rumex</td>
<td>1000Cst</td>
</tr>
<tr>
<td></td>
<td>5000Cst</td>
</tr>
<tr>
<td>B&amp;L</td>
<td>1300Cst</td>
</tr>
<tr>
<td></td>
<td>5700Cst</td>
</tr>
<tr>
<td>Arcad</td>
<td>1300 Cst</td>
</tr>
<tr>
<td></td>
<td>5500 Cst</td>
</tr>
</tbody>
</table>
SmartSil 1000/5000

- SmartSil is an ultra purified silicone oil which has lowest value of concentration of toxic elements and low molecular weights
- Not emulsification
- SmartSil has the highest interface tension
- SmartSil is indicated in prolonged tamponade
- There is no diffusion or absorption of the silicone out of the eye
Thank you!

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