

# SOP 013

2000 cSt SILICONE OIL PACK COMPATIBLE WITH  
MILLENNIUM™, STELLARIS® PC

HIGH PURITY STERILE SILICONE OIL 2000 cSt, 10 ML, AND CONNECTION TUBING

## SILICONE OIL

	RS-OIL ECS 2000	ECT connection to Millennium™, Stellaris® PC
<b>Ingredient</b>	100% silicone oil, obtained from the mixture of long and short molecular chains (100% polydimethylsiloxane)	<ul style="list-style-type: none"> <li>› tubing: medical grade PVC</li> <li>› connections: polycarbonate + acetal</li> </ul>
<b>Viscosity (25°C)</b>	1900 - 2100 cSt	not applicable
<b>Specific gravity (25°C)</b>	0.967 - 0.975	not applicable
<b>Refractive index (25°C)</b>	1.40	not applicable
<b>Acidity index</b>	< 0.15 ml NaOH 0.01 N	not applicable
<b>Heavy metals</b>	< 5 ppm	not applicable
<b>Phenolic compounds</b>	< 0.20 (250 - 270 nm)	not applicable
<b>Volatility (10g/24h/150°C)</b>	< 0.10 %p/p	not applicable
<b>Bacterial endotoxins</b>	< 0.5 EU/ml	not applicable
<b>Cytotoxicity Test</b>	Non-cytotoxic according to ISO 10993-5, direct contact test performed on two cell lines: <ul style="list-style-type: none"> <li>- retinal pigment epithelial cells (ARPE-19)</li> <li>- mouse fibroblasts cells (BALB 3T3 clone A31)</li> </ul>	not applicable
<b>Form</b>	sterile fluid	sterile solid
<b>Volume</b>	10 ml	not applicable
<b>Packaging</b>	unbreakable syringe, chemically inert, with adapter, in medical pouch	pouch
<b>Sterilization</b>	moist heat according to EN ISO 17665-1	ethylene oxide according to EN ISO 11135-1
<b>Storage temperature</b>	room temperature	room temperature
<b>Expiry date</b>	36 months	60 months
<b>Intended use</b>	intraocular tamponade during vitreoretinal surgery	connection tubing to injection system
<b>Class</b>	medical device	medical device
<b>GMDN code</b>	P 45125	P 47240
<b>CND code</b>	Q02030202	Q0299
<b>MD registration number</b>	104604/R	
<b>Medical device class</b>	pack in compliance with Article 12 of the directive 93/42/EEC	
<b>Marchio CE</b>	CE 0546	CE 0546

The pack includes 1 RS-OIL ECS 2000, in a polymeric syringe, for long-term replacement of the vitreous humor extracted during vitreoretinal surgery, and 1 ECT connection tubing. Product warrants a stable tamponade over the time and reduced incidence of complications. The ready-to-use syringe, made of inert, plastic and silicone oil compatible material, connects to Millennium™, Stellaris® PC by means of the ECT connection tubing, and increases patient safety by reducing the risk of breakage during handling or surgery.

**Ref.:** SOP 013

**Contents:**

- › RSO 013-00
- › ECT 002-00

**GS1-128 barcode**

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OPHTALMO  
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