

HIGH PURITY  
STERILE SILICONE  
OIL 1000 CS, 10 ML,  
AND CONNECTION TUBING

# SOP 1000

SILICONE OIL PACK COMPATIBLE WITH MILLENNIUM™

## SILICONE OIL



SOP, Silicone Oil Pack, includes 1 RS-OILECS, highly purified silicone oil (100% pure polydimethylsiloxane), 1000 cS, 10 ml, sterile and apyrogenic, packaged in pre-filled syringe, intended for long-term replacement of the vitreous humour 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™ by means of the ECT connection tubing, and increases patient's safety by reducing the risk of breakage during handling or surgery.

**Ref.:** SOP 002-00

**Contents:**

- ▶ Package includes 1 high purity sterile silicone oil 1000 cS 10ml-syringe (100% polydimethylsiloxane)
- ▶ 1 insert
- ▶ 4 labels for product traceability
- ▶ 1 sterile connection tubing to Millennium™

**EAN 13 barcode:**

802111800011

	RS-OIL ECS 1000	ECT connection to Millennium™
<b>Ingredient</b>	100% silicone oil (100% polydimethylsiloxane)	▶ medical grade PVC ▶ polycarbonate + acetal
<b>Viscosity (25°C)</b>	1000 cS	
<b>Specific gravity (25°C)</b>	0,967 - 0,975	-
<b>Refractive index (25°C)</b>	1,40	-
<b>Volatility (1 g/2 h/150°C)</b>	< 0,1%	-
<b>Form</b>	fluid	-
<b>Volume</b>	10 ml	solid
<b>Packaging</b>	unbreakable syringe in medical pouch	-
<b>Sterilization</b>	moist heat according to UNI EN 554:1996	gamma rays according to EN ISO 11137:2006 on ethylene oxide according to EN ISO 11135-1:2008
<b>Storage temperature</b>		room temperature
<b>Expiry date</b>		24 months
<b>Intended use</b>	intraocular tamponade during vitreoretinal surgery	connection to injection system
<b>Class</b>		medical device
<b>GMDN code</b>		P 45125
<b>MD registration number</b>		3613/R
<b>Medical device class</b>		IIb
<b>CE mark</b>		CE 0546

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