

HIGH PURITY  
STERILE SILICONE  
OIL 5000 CS, 10 ML,  
AND CONNECTION TUBING

# SOP 5000

SILICONE OIL PACK COMPATIBLE WITH LUER, ASSISTANT

## SILICONE OIL



	RS-OIL ECS 5000	Connection to Luer, Assistant
<b>Ingredient</b>	100% silicone oil (100% polydimethylsiloxane)	polyethylene, lupolen, master white
<b>Viscosity (25°C)</b>	5000 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	solid
<b>Volume</b>	10 ml	-
<b>Packaging</b>	unbreakable syringe in medical pouch	pouch
<b>Sterilization</b>	moist heat according to EN ISO 17665-1:2006	gamma rays according to EN ISO 11137:2006 or ethylene oxide according to EN ISO 11135-1:2008
<b>Storage temperature</b>		room temperature
<b>Expiry date</b>	24 months	36 months
<b>Intended use</b>	intraocular tamponade during vitreoretinal surgery	connection tubing to injection system
<b>Class</b>		medical device
<b>GMDN code</b>	P 45125	P 47240
<b>MD registration number</b>		5284
<b>Medical device class</b>	IIb	Is
<b>CE mark</b>	CE 0546	CE 0546

SOP, Silicone Oil Pack, includes 1 RS-OIL ECS, highly purified silicone oil (100% pure polydimethylsiloxane), 5000 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 Luer, Assistant by means of the ECT connection tubing, and increases patient's safety by reducing the risk of breakage during handling or surgery.

**Ref.:** SOP 008-00

**Contents:**

- ▶ 1 RS-OIL ECS RSO 007-00
- ▶ 1 ECT 001-01

**EAN 13 barcode:**

08021118000869

**ALCHIMIA**

Viale Austria, 14  
35020 Ponte S.Nicolò (PD)  
Italy

Tel. +39 049 8962074 / 64  
Fax +39 049 8962071

www.alchimiasrl.com  
info@alchimiasrl.com