

SOP 004

5000 cSt SILICONE OIL PACK COMPATIBLE WITH
MILLENNIUM™, STELLARIS® PC

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

SILICONE OIL

	RS-OIL ECS 5000	ECT connection to Millennium™, Stellaris® PC
Ingredient	100% silicone oil, obtained from the mixture of long and short molecular chains (100% polydimethylsiloxane)	<ul style="list-style-type: none"> › tubing: medical grade PVC › connections: polycarbonate + acetal
Viscosity (25°C)	4750 - 5250 cSt	not applicable
Specific gravity (25°C)	0.967 - 0.975	not applicable
Refractive index (25°C)	1.40	not applicable
Acidity index	< 0.15 ml NaOH 0.01 N	not applicable
Heavy metals	< 5 ppm	not applicable
Phenolic compounds	< 0.20 (250 - 270 nm)	not applicable
Volatility (10g/24h/150°C)	< 0.10 %p/p	not applicable
Bacterial endotoxins	< 0.5 EU/ml	not applicable
Cytotoxicity Test	Non-cytotoxic according to ISO 10993-5, direct contact test performed on two cell lines: - retinal pigment epithelial cells (ARPE-19) - mouse fibroblasts cells (BALB 3T3 clone A31)	not applicable
Form	sterile fluid	sterile solid
Volume	10 ml	not applicable
Packaging	unbreakable syringe, chemically inert, with adapter, in medical pouch	pouch
Sterilization	moist heat according to EN ISO 17665-1	ethylene oxide according to EN ISO 11135-1
Storage temperature	room temperature	room temperature
Expiry date	36 months	60 months
Intended use	intraocular tamponade during vitreoretinal surgery	connection tubing to injection system
Class	medical device	medical device
GMDN code	P 45125	P 47240
CND code	Q02030202	Q0299
MD registration number	104544/R	
Medical device class	pack in compliance with Article 12 of the directive 93/42/EEC	
Marchio CE	CE 0546	CE 0546

The pack includes 1 RS-OIL ECS 5000, 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.

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Contents:

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GS1-128 barcode

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