

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

SOP 003

5000 cSt SILICONE OIL PACK COMPATIBLE WITH
CONSTELLATION®, ASSOCIATE® 2500

SILICONE OIL



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 Accurus®, Constellation®, Associate® 2500 by means of the ECT connection tubing, and increases patient's safety by reducing the risk of breakage during handling or surgery.

	RS-OIL ECS 5000	ECT connection to Accurus®, Constellation®, Associate® 2500
Ingredient	100% silicone oil (100% polydimethylsiloxane)	<ul style="list-style-type: none"> > tubing: medical grade PVC > connections: polycarbonate + acetal
Viscosity (25°C)	4750 – 5250 cSt	-
Specific gravity (25°C)	0.967 - 0.975	-
Refractive index (25°C)	1.40	-
Acidity index	< 0.15 ml NaOH 0.01 N	-
Heavy metals	< 5 ppm	-
Phenolic compounds	< 0.20 (250 – 270 nm)	-
Bacterial endotoxins	< 0.5 EU/ml	-
Volatility (10g/24h/150°C)	< 0.10% p/p	-
Form	fluid	solid
Volume	10 ml	-
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	24 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
CE mark	CE 0546	CE 0546
Medical device class	pack in compliance with Article 12 of the directive 93/42/EEC	
MD registration number	104543/R	

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