

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

SOP 5000

SILICONE OIL PACK COMPATIBLE WITH ORBIT, OS3, PHARO™

SILICONE OIL



SOP, Silicone Oil Pack, includes 1 RS-OILECS, 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 Orbit, OS3, Pharo™ by means of the ECT connection tubing, and increases patient's safety by reducing the risk of breakage during handling or surgery.

Ref.: SOP 006-00

Contents:

- ▶ 1 high purity sterile silicone oil 5000 cS 10ml-syringe (100% polydimethylsiloxane)
- ▶ 1 insert
- ▶ 4 labels for product traceability
- ▶ 1 sterile connection tubing to Orbit, OS3, Pharo™

EAN 13 barcode:

8021118000616

	RS-OIL ECS 5000	ECT connection to Orbit, OS3, Pharo™
Ingredient	100% silicone oil (100% polydimethylsiloxane)	▶ medical grade PVC ▶ polycarbonate + acetal
Viscosity (25°C)	5000 cS	-
Specific gravity (25°C)	0,967 - 0,975	-
Refractive index (25°C)	1,40	-
Volatility (1 g/2 h/150°C)	< 0,1%	-
Form	fluid	solid
Volume	10 ml	-
Packaging	unbreakable syringe in medical pouch	pouch
Sterilization	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
Storage temperature		room temperature
Expiry date		24 months
Intended use	intraocular tamponade during vitreoretinal surgery	connection tubing to injection system
Class		medical device
GMDN code		P 45125
MD registration number		35882/R
Medical device class		IIb
CE mark		CE 0546

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