

HIGH PURITY STERILE
SILICONE OIL 5000 CST,
10 ML IN SYRINGE
WITH ADAPTER

RS-OIL ECS 5000

EASY CONNECTION SYRINGE

SILICONE OIL



| RS-OIL ECS 5000 | |
|-----------------------------------|--|
| Ingredient | 100% silicone oil (100% polydimethylsiloxane) |
| 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 |
| Volume | 10 ml |
| Packaging | chemically inert unbreakable syringe with adapter in medical pouch |
| Sterilization | moist heat according to EN ISO 17665-1 |
| Storage temperature | room temperature |
| Expiry date | 36 months |
| Intended use | intraocular tamponade during vitreoretinal surgery |
| Class | medical device |
| GMDN code | P 45125 |
| MD registration number | 3607/R |
| Medical device class | IIb |
| CE mark | CE 0546 |

RS-OIL ECS is highly purified silicone oil (100% pure polydimethylsiloxane), 5000 cSt, 10 ml, sterile and apyrogenic, packaged in pre-filled syringe, intended for long-term replacement of the vitreous humour extracted during vitreoretinal surgery. Product warrants a stable tamponade over the time and reduced incidence of complications. The ready-to-use syringe is made of inert, plastic and silicone oil compatible material to increase patient's safety by reducing the risk of breakage during handling or surgery.

Ref.: RSO 007-00

Contents:

- ▶ 1 chemically inert unbreakable syringe of high purity sterile RS-OIL ECS 5000 (100% high purity, sterile silicone oil 5000 cSt, 10 ml)
- ▶ 1 plunger
- ▶ 1 insert
- ▶ 4 labels for product traceability

GS1 – 128 (EAN 128)

barcode including

EAN 13 barcode:

8021118000098

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