AUROSIL

(High Quality, Purified Silicone Oil)

A Tamponade to treat Complex Retinal Detachments



- Greater stability
- Reduced emulsification due to a high degree of purification and low level of reactive -OH end groups
- Less tissue impregnation
- Subject to all physical and chemical analysis (H-NMR spectral test, gel permeation chromatography study and gas chromatography) to ensure purity level
- Low level of catalyst impurities minimize the risks of interactions with the ocular environment
- Quality product with a proven track record

DESCRIPTION

AUROSIL is fractionated, purified, sterile and apyrogenic silicone oil designed for prolonged tamponade after surgical treatment for severe retinal detachment.

CHARACTERISTICS

1000 cSt ±50 cSt Viscosity (at 25°C) Refractive index (at 35°C) 1.3900 - 1.4050Specific Gravity (at 30°C) 0.967 - 0.975Average Molecular Weight (daltons) $44,000 \pm 1000$

Poly Dispersion Index 2.5 Toxic Residue Nil Content of -OH-end groups <70 ppm

INDICATIONS

Retinal detachment with giant tear, retinal detachment with proliferative vitreo retinopathy (PVR), proliferative diabetic retinopathy (PDR) and traumatic retinal detachment.

CONTRAINDICATION

Pseudophakic patients with silicone intraocular lens (silicone oil can chemically interact and opacify silicone elastomers).

PRECAUTIONS

As with any surgical procedure, posterior segment surgery using AUROSIL presents risks which the surgeon must evaluate.

Do not resterilize. Single use product only. Do not use if packaging that ensures sterility is damaged. Do not use after expiry date.

DIRECTIONS

In aseptic conditions decant the contents of the bottle into a sterile syringe. Place the syringe in a syringe driver in order to facilitate the injection. Plug in the infusion terminal to the tip of the syringe. Inject slowly.

During withdrawal, avoid leaving silicone bubbles in the vitreo-retinal cavity. Once AUROSIL is removed from the patient's eye it should be treated as any human biological product.

ADVERSE REACTIONS

The most common adverse reactions include cataract, anterior chamber oil migration, keratopathy and glaucoma. Other adverse reactions include optic nerve atrophy, rubeosis iritis, temporary IOP increase, macular pucker, vitreous hemorrhage, phthisis, traction detachment, angle block, subretinal strands, retinal rupture, endophthalmitis, subretinal silicone oil, choroidal detachment, aniridia and cystoid macular edema. Opacification of silicone IOL has been reported (in-vitro).

ADMIXTURE INCOMPATIBILITY

Do not admix with any other substance prior to injection

STORAGE

Store between 2°C and 35°C.

SUPPLY

10 ml vial in a sterile pouch



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