



## Silicone oil in vials

Polydimethylsiloxane - 10 e 15cc vial - sterile disposable for prolonged use

### Instructions

The PDMS is an oily liquid with high viscosity intended to replace the vitreous humor in vitrectomy surgery with long residence time in the eye, usually longer than 30 days.

### Use

This device should only be used by an Ophthalmic Surgeon Specialist, expert in vitreo-retinal surgery.

The PDMS can be inserted into the vitreous cavity only after carefully removing the central and peripheral vitreous.

Before infusion, however, it is necessary to ensure that there are no parts of the vitreous free, or that the vitreous could mix with the PDMS itself. Once verified this situation, make sure that there are no holes or slots on the retina placed in a position allowing the capture of part of the material in the retina-choroidal space.

### Mode of operation

Make sure that the packaging is intact. Open the package of PDMS and remove the seal completely, removing the wire cage. Clean with alcohol the exposed rubber stopper and

after removing it, pour the contents into a sterile plastic syringe with which to inject into the eye with mechanical or pneumatic means. Due to the high viscosity of the liquid, it is not recommended to inject it by hand.

It is possible to inject the oil either with a blunt cannula (it is recommended to use special cannulas, specially made for the infusion of viscous fluids), or with the help of a special inserter, through the cannula infixed in the sclera and normally used to infuse saline solution into the eye during the vitrectomy.

It is almost impossible to ensure that during the infusion the intraocular pressure is correct (20-40 mmHg.), it will be necessary to check the correct papillary spraying and possible compression of the optic nerve, and in that case to suspend the infusion immediately.

### Composition

PDMS contains Polydimethylsiloxane fluid.

**Formula** [-Si(CH<sub>3</sub>)<sub>2</sub>O-]<sub>n</sub>

**Refraction index** 1,404 @ 24°C

**Density** 0,965 gr/ml @ 24°C

**Viscosity** 1000/1300/2000/5000 centistokes @ 25°C

**Classification** Medical Device - class IIb

### Warnings

The contact with the corneal endothelium is dangerous, take precautions so that it is absolutely avoided !! It is also dangerous to inject the substance into the retino-choroidal space !!

The devices must be used in the sterile field, only by ophthalmologists experienced in vitreo-retinal surgery.

The devices must only be used by suitably trained staff.

Before use, read and understand the instructions for use of the equipment.

Use only if the package is intact and immediately after its opening.

The control of the package must be done with care.

Keep the device preferably at temperatures around 20 °C ± 5 °C and protected from direct sunlight.

It is also suggested the adoption of the following operating steps:

clean the outside of the pack out of the surgical room;

wear suitable clothing;

bring the envelope in the area of use;

open the package;

remove the device without touching the outside of the package;

take each component and apply it immediately to avoid contact with potentially contaminated parts;

do not leave it unattended.

For disposal after use, follow the procedures for hospital waste and / or materials contaminated with bacterial and / or viral infections; in case of not covered abnormal situations, avoid direct contact and manipulate the device with suitable equipment and means of protection to avoid any potential contamination of people and the environment.

During the infusion of viscous liquids it is imperative the control of intraocular pressure.

The maximum allowable pressure for viscous fluid infusion is 5atm (70psi).