



Silicone oil in plastic syringe (refill)

Polydimethylsiloxane - 10cc plastic syringe - sterile disposable for prolonged use

Instructions

The PDMS is an oily liquid with high viscosity intended to replace the vitreous humor in the 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 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 luer lock cap seal.

The device can be used according to two operating modes, either as refill to recharge a pneumatic syringe exhausted during the infusion, or as a manual infusion system.

In the first case, that is charging a depleted pneumatic syringe, connect the syringe in free line of the tap (if you use that of the saline solution, take care to remove the re-

sidual water and then fill the dead space with silicone). Screw the syringe, turn the knob to the link and press on the piston up to a full charge, then turn back the tap at infusion position. Continue referring to the instructions contained in the box of pneumatic infusion syringe.

In the second case, that is using it as a manual infusion system, it's necessary to be particularly careful and take in account the high viscosity of the liquid, it is advisable to limit the use of manual infusion with silicone oil at 1000 and 1300 cSt viscosity; we do not recommend the use of manual infusion with silicone oil at 2000 and 5000 cSt viscosity.

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 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	$[-Si(CH_3)_2O-]_n$
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

Contact with corneal endothelium is very dangerous, take precautions to avoid that!!

Do not inject substance into retinal choroids space!!

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

The devices must be used only by trained personnel.

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 of $20 \pm 5 \text{ }^\circ\text{C}$ and protected from direct sunlight.

It is also suggested the adoption of the following operation phases:

- clean the outside of the pack out of the hall of intervention;
- wear suitable clothing;
- bring the package in the area of use;
- open the package;
- pick the device without touching the outside of the package;
- pick each other component and apply it immediately to avoid contact with potentially contaminated parts;
- do not leave it unattended.

For disposal, follow the procedures for hospital waste and / or materials contaminated by bacterial and / or viral infections, in the event of abnormal situations always avoid direct contact and manipulate the device with suitable equipment and means of protection adapted to avoid any potential contamination of people and the environment.

During the infusion of viscous liquids is imperative the control of intraocular pressure. The maximum allowable pressure for the operations of infusion viscous liquids is 5 bar (70psi).