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PDMS GLASS SYRINGE

1. INSTRUCTIONS

PDMS is a class IIb implantable medical device. It is a viscous fluid used in vitrectomy operations, i.e. the removal of the vitreous membrane. It is injected into the vitreous chamber in order to replace the vitreous humor and promote the healing processes of the retina. It has a residence time of more than 30 days, after which it must be surgically removed.

2. INFORMATION REQUIRED BEFORE USING THE DEVICE

This medical device must be used by medical professionals, and ophthalmologists experienced in vitreous-retinal surgery, in a sterile field.

PDMS is inserted into the vitreous cavity only after carefully removing the central and peripheral vitreous. Before infusion, however, it must be ensured that there is no free vitreous or that it may mix with the PDMS itself. If this is the case, make sure that there are no holes or slits in the retina in a position that would allow some of the material to pass into the subretinal space.
The oil is removed by replacing it with a balanced saline solution, air or gas. The most commonly used route is the pars plana; in aphakic eyes - i.e. without a crystalline lens - removal can also take place through micro-incisions at sclero-corneal limbus level.

Warnings and Precautions:

- Do not use the device for purposes other than those indicated
- This medical device is single-use.
- Use only in sterile field
- Do not use the product after the expiry date
- Make sure the packaging is intact: sterility is guaranteed only if the packaging is intact. Do not use the device if the packaging is damaged
- Do not re-sterilise the accessories. Re-sterilisation could lead to material degradation processes
- The accessories contained are sterile and single-use only. Reuse of the accessories can lead to bacterial contamination events, with serious consequences for the patient
- Before beginning the surgery, check the efficiency of each component of the infusion system (fittings, tubing) and of the pressure source, which must correspond to the equipment's specifications
- Use the product immediately after opening
- The maximum permissible pressure for viscous liquid infusion surgeries is 5atm (70psi); do not exceed this value during infusion, to avoid failure and/or rupture along the infusion line
- During infusion, it is paramount to keep intraocular pressure under check
- Care must be taken not to inject silicone oil into the sub-retinal space.

Contraindications

Contact with the corneal endothelium is dangerous: take appropriate precautions to avoid it.
Do not inject silicone oil into the sub-retinal space. The persistence of PDMS in the intraocular site for long periods causes side effects that are well described in the literature, including cataracts and glaucoma.

It is the surgeon's responsibility to check for and manage any such side effects during post-operative follow-up.
All types of PDMS, when injected into the eye, have a tendency to form an emulsion with the aqueous humour present in the intraocular site.

Recommendations

- It is recommended to inject PDMS with a cannula to avoid possible trauma to the bulb
- However, check the optic papilla during infusion to ensure that the vessels are properly supplied with blood
- PDMS is intended to stabilise the retina after vitreous removal
- When used as a manual infusion system, the high viscosity of the liquid must be taken into account
- Due to the high viscosity of the liquid, it is advisable to limit the use of manual infusion to viscosities of 1000 and 1300 cSt, avoiding its use in cases of 2000 cSt and especially 5000 cSt viscosity
- The use of specially designed cannulae for infusing viscous fluids is recommended
- Check for any compression of the optic nerve and, if necessary, immediately stop the infusion

3. HOW TO USE

REF. MMD-665, MMD-686, MMD-696 and MMD-675
The package contains a glass syringe (10cc) pre-filled with silicone oil, a 23 G cannula and a luer lock adapter. The syringe is equipped with a conical luer connection. The fastening system (Lock) is supplied separately in the bag.

- remove the sealing plug and insert the Lock fastener into the luer cone
- push it until it clicks
- fit the infusion line tightly, or an infusion needle.

REF. MMD-665A, MMD-686A, MMD-696A and MMD-675A
The package contains a glass syringe (10cc) pre-filled with silicone oil and already fitted with a built-in metal luer lock and a 23 G cannula.

- remove the sealing plug
- fit the infusion line tightly, or an infusion needle.

4. POSSIBLE ADVERSE EFFECTS

Vitreoretinal surgery can lead to post-operative complications. Some of the post-operative complications could be:

- Cataract
- Acute or chronic glaucoma
- Endophthalmitis, internal eye infection may require removal of the eyeball
- Persistence of one or more silicone oil bubbles in the glass chamber
- Vitreous-retinal reproliferation (PVR)
- Hypertone (increased eye pressure)
- Transient or permanent decrease in eye pressure
- Visual field defects.

It is the surgeon's responsibility to properly inform the patient about the risks and benefits of the surgery.

REPORTING ACCIDENTS AND ADVERSE EFFECTS

In the event of an accident and/or adverse effect occurring as a result of the use of the PDMS product, the healthcare professional must report the event to the competent authority of the Member State in which it occurred, to the distributor and to the medical device manufacturer (incidenti-e-reclami@micromed.it). In the report, describe the event in detail and indicate the UDI code of the device involved.

If you have any complaints or feedback about the product, please send an email to incidentiereclami@micromed.it.

5. STORAGE

The package containing PDMS should not be subjected to sudden changes in pressure and temperature.
Store at room temperature, in a cool, dry place, away from direct sunlight.
Do not use the product if the inner packaging that guarantees sterility is not intact.
Do not use the product after the expiry date.
Dispose of the product as hospital waste.

6. PACKAGE CONTENTS AND AVAILABLE FORMATS

Each package contains a glass syringe (10cc) pre-filled with silicone oil and a 23 G cannula.

The product is available in different variants depending on the viscosity of the silicone oil and the type of glass syringe included:

Syringe type	900-1100 cSt	1170-1430 cSt	1800-2200 cSt	4500-5500 cSt
PC Luer-Lock connector, detachable	MMD-665	MMD-686	MMD-696	MMD-675
Metal Luer-Lock connector, integrated	MMD-665A	MMD-686A	MMD-696A	MMD-675A

PDMS consists of liquid polydimethylsiloxane.

Chemical and physical characteristics

Formula	[-Si (CH3)2 O-]n
Melting point	-25 °C
Density	0.97 g/ml
Refractive index	1.4035
Appearance: Liquid	(colourless)
Smell	typical
CAS No.	63148-62-9

7. MANUFACTURER'S DATA

The manufacturer of the PDMS medical device is

Micromed Srl
Registered Office: Viale Val Padana, 126 - 00141 - Rome - Italy
Production Site: Via Oberdan, 21 - 00013 - Fonte nuova (Rome) - Italy
For information, please write to: info@micromed.it
For incidents, complaints and feedback, please write to: incidentiereclami@micromed.it

The PDMS - GLASS SYRINGE medical device is CE 0373 certified.

8. SYMBOLS

Symbol	Description
	Manufacturer
	Product code
	Batch number (REF-SSAA)
	Date of manufacture (YYYY-MM)
	Expiry date (YYYY-MM)
	Ethylene Oxide sterilised
	Dry heat sterilised
	Single-use device
	Does not contain latex
	Caution: read the package leaflet carefully
	Do not re-sterilize
	Do not use if package is open or damaged
	Keep away from sunlight
	Store in a dry place
	UDI (AIDC format) - GS1 - DataMatrix (1) UDI-DI (17) Expiry date (10) Batch number

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