



INSTRUCTIONS FOR USE PRESSURE MONITORING LINE

*Please Read All Instructions Carefully Before Use (Sterile, for single use only)

SMDPL/IFU/PML/01. Rev. No.:00, Dt. 12.08.2023

PRODUCT DESCRIPTION:

Pressure monitoring line is made of clear and non-toxic PVC that is kink resistant tubing. Pressure monitoring line specifications facilitates optimum dynamic response; it is latex free and available as sterile in non phylogenetic form. It is highly accurate and monitors the fluent blood pressure as required. Pressure monitoring line is used for observing the pressure through extended medical soft, kink resistant PVC tubing which ensures smooth fluid movement.

Pressure Monitoring Line (SMD 706 MF, SMD 706 MM, SMD 706 FF):

A device designed as a PVC tubing set used for the external connection to a transducer, either directly or from an intermediate stopcock, of catheters used for invasively measuring blood pressure.

Pressure Monitoring Line Spiral (SMD 715 MF, SMD 715 MM, SMD 715 FF):

A device designed as a PE Spiral tubing set used for the external connection to a transducer, either directly or from an intermediate stopcock, of catheters used for invasively measuring blood pressure.

INTENDED PURPOSE:

Used for the external connection to a transducer, either directly or from an intermediate stopcock, of catheters used for invasively measuring blood pressure for short term use.

INDICATIONS:

Pressure Monitoring Line is primarily used in cardiac surgeries for invasive blood pressure monitoring and connection between syringe infusion pump & patient.

CONTRAINDICATIONS:

- Infection at the site of insertion
- Collateral circulation is compromised
- Vessel arteritis
- Presence of peripheral arterial vascular insufficiency
- Patients having coagulopathies or taking medications that prevent normal coagulation.

LIMITATION

N/A

INTENDED USER

Doctors or qualified healthcare professionals only.

INTENDED PATIENT POPULATIONS

Children and Adults.

DIRECTIONS FOR USE:

- Read the Instructions Carefully
- Choose the appropriate size of the device.
- Open the package from the peel-open area and remove the device.
- Check the pressure line and flush it with normal saline before use.
- Connect the luer connector with other devices, and eliminate air in the tube before connection
- Do not use it if the package is damaged or not well sealed

WARNING:

The use of this product is restricted to a qualified Doctor or Healthcare professional only.

PRECAUTIONS AND CAUTIONS:

- Prior to using read entire instructions for use. Failure to do so may result in severe patient injury.
- **STERIMED DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES FROM IMPROPER USE.**
- Do not clean or Re-use the device,
- For single Patient use only.

- Discard after Single use.
- The product should be used immediately after opening the packing.
- Do not use with a stylet or guide wire
- Do not use the device after expiry Date mentioned on the Label.
- If the patient is sensitive or allergic to PVC, do not use the device.

ADVERSE EFFECTS:

- Infection
- Lack of collateral circulation resulting in vascular insufficiency
- Formation of a hematoma
- Formation of an arteriovenous (AV) fistula
- Stenosis of vessel
- Blood loss

CLINICAL BENEFITS:

- Monitoring improves BP control
- Improve prevention or regression of organ damage
- Protection from major cardiovascular complications
- Reduced blood pressure
- Improve hypertension control
- (CEC) rate – Clotting of the Extracorporeal circuit - Low

RESIDUAL RISKS:

- Formation of an arteriovenous (AV) fistula
- Infection

SUPPLY:

Male to Female - SMD 706
MF



Male to Male - SMD 706
MM



Female to Female - SMD
706 FF



Spiral (Male to Female) -
SMD 715 MF



Spiral (Male to Male) - SMD
715 MM





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Spiral (Female to Female) -
SMD 715 FF



MATERIALS USED:

Pressure Monitoring Line (SMD 706 MF, SMD 706 MM, SMD 706 FF):

Component	Material	Specification/Grade
PVC Tube	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Connectors (Male & Female)	ABS (Acrylonitrile Butadiene Styrene) Compound	Medical Grade
Connector Cap (Male Connector & Female Connector)	PP (Poly Propylene)	Medical Grade

Pressure Monitoring Line Spiral (SMD 715 MF, SMD 715 MM, SMD 715 FF):

Component	Material	Specification/Grade
PVC Tube	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Connectors (Male & Female)	ABS (Acrylonitrile Butadiene Styrene) Compound	Medical Grade
Connector Cap (Male Connector & Female Connector)	PP (Poly Propylene)	Medical Grade

STERILITY:

This device is sterilized by ethylene oxide gas. Do not re-sterilize, and do not reuse. Do not use it if the package is opened or damaged. Discard opened, unused device.

STORAGE:

The Device should be stored in their original box in a cool and dry place between 5 to 45° C, preferably away from direct and indirect sources of light and heat. Do not use after expiry.

DEVICE DISPOSAL:

Used Devices may be contaminated with infectious and/or other hazardous materials. Discard used tubes in the container meant for infectious waste. Unused expired product should be disposed of as per local regulations.

NOTE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

SYMBOLS:



Catalogue No.



See instructions
for Use



Cautions



Keep Dry



Do not use it if the
packaging is
damaged.



Sterile Barrier
System



Single-Use



Do not Re-
sterilize



Batch / Lot No.



Ethylene Oxide
Sterilized



Date of Mfg.



Latex Free



Date of Exp.



Medical Device



Avoid Direct
Sunlight



Keep in a dry
place between
5°C to 45°C



Phthalate Free



Pyrogen Free



Unique Device
Identifier



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EN ISO 13485:2016 Certified Company

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