IFU of
Pressure Monitoring Tubing/Line
Manufactured by Mais India Medical Devices Pvt. Ltd.

General Device Description:
The Pressure Monitoring Tubing is a sterile, single-use, flexible medical tubing designed to extend the fluid pathway between an infusion/transfusion system and a vascular access device. It comprises medical-grade transparent tubing fitted with standard Luer lock connectors to ensure secure, leak-free connections with compatible infusion sets, syringes, and catheters.

Product Name:
Pressure Monitoring Tubing/Line

Brand Name:
1. MAIS HIGH PRESSURE EXTENSION LINE™
2. UV Maisprotect Line™
3. Hi-EX LINE™

Variants:
1. High Pressure M/F
2. High Pressure M/F-Spiral
3. High Pressure M/M
4. High Pressure M/M-Spiral
5. Spiral Extension Line with fixed one Needle Free Connector
6. High Pressure F/F
7. High Pressure F/F-Spiral.

Sizes:
10 to 200cm.

Intended Use:
Pressure Monitoring Tubing is a device to be incorporated between infusion line and the indwelling Venipuncture device to minimize disturbance at cannulation/insertion sites by taking the movement of away from cancellation /insertion site. Luer lock and threaded female ports are provided to facilitate safe and secure connection to the Luers.

Materials of Construction:

Sr. No.	Components	Material
1.	Tube (DEHP Free)	PVC
2.	Male Luer Connector	PC (Lipid Resistant)
3.	White Cap	HDPE
4.	Female Connector	PC (Lipid Resistant)
5.	Threaded Stopper	HDPE

Indications for use:
The Pressure Monitoring Tubing is indicated for use in patients requiring an extended sterile fluid pathway for the administration of intravenous fluids, medications, or blood/blood components through an established vascular access device.

Contra Indications:
• Do not use in patients with known hypersensitivity to any material of the device.
• The Pressure Monitoring Tubing shall not be used in place of a vascular access device. It is an accessory and must only be connected to an appropriate, compatible vascular access device.
• The Pressure Monitoring Tubing shall not be used for delivery of highly viscous lipid emulsions, parenteral nutrition admixtures, or other high-viscosity fluids.

Intended Patient Population:
All patient population.

Intended User:
Qualified doctor or a paramedic.

Use environment:
Proper Healthcare Setup.

Instruction for use:
• Confirm that the product is within its expiry date and that the sterile packaging is intact and free from damage.
• Open the package using aseptic technique.
• Attach the proximal end of the tubing to the prescribed infusion system or fluid source.
• Initiate fluid flow to fully prime the tubing and eliminate all air.
• Close clamps or stopcocks after priming until the tubing is connected to the patient.
• Remove the distal protective cap and connect the tubing securely to the vascular access device using aseptic technique.
• Ensure all connections are tight to prevent leakage or disconnection.
• Periodically inspect the tubing and connections during use for kinks, air bubbles, leakage, or contamination.
• Replace the tubing if any defect or contamination is detected.
• Upon completion of therapy, close all clamps or stopcocks.
• Disconnect the tubing using aseptic technique.
• Dispose of the used tubing and associated materials in accordance with applicable biomedical waste regulations.

Intended Clinical Benefits to the patients:
Direct Clinical Benefits: -
• Ensures secure and reliable extension of the IV fluid pathway, enabling uninterrupted fluid administration.
• Maintains lumen patency and consistent flow characteristics, reducing the risk of occlusion, backflow, or flow variability during infusion therapy.
• Minimizes the risk of catheter-related complications by allowing connection/disconnection away from the vascular access site.
• Supports aseptic fluid administration by reducing the need for frequent direct handling of the primary catheter hub, thereby lowering contamination risk.
• Enables safe administration of IV fluids and medications, maintaining system integrity under routine clinical pressures.
Reduces the risk of air ingress when used as part of a properly primed IV system.

Indirect Clinical Benefits: -
• Enhances patient comfort and mobility by providing additional tubing length, allowing flexible positioning without disturbing the IV access site.
• Reduces mechanical stress and traction on the catheter, helping to minimize site irritation and vessel trauma.
• Lowers the likelihood of accidental dislodgement or line disruption due to patient movement or handling.

Clinical Safety:
• Device Design and Material Safety.
• Biocompatible products.
• Our device is a single use device.
• Our product is non-toxic, sterile & non-pyrogenic.

Performance characteristics:
• The Pressure Monitoring Tubing maintains uniform and uninterrupted fluid flow under standard infusion conditions, supporting accurate delivery of IV fluids, medications, and blood products.
• The tubing exhibits high resistance to kinking and compression, ensuring lumen patency and minimizing flow interruptions during routine patient movement.
• Materials used in the fluid pathway are compatible with commonly administered IV solutions and medications, supporting broad clinical applicability.
• When connected correctly, the Pressure Monitoring Tubing maintains a secure, sterile fluid pathway that minimizes the risk of contamination and infection.

Accessories which can be used with the device:
Pressure Monitoring Tubing does not have any accessories provided along with the kit. But it can be used along with Peripheral IV Catheters, Infusion Delivery Systems, IV Sets and Needle Free Connectors.

Warnings:
• For use by trained healthcare professionals only.
• The product should not be reprocessed.
• Improper transport and handling may cause structural and/or functional damaged to device or packaging.
• The product is guaranteed sterile, non-pyrogenic and non-toxic if package is not opened or damaged.
• Do not clean or resterilize.
• Do not expose to heat or direct sunlight.
• Use the product immediately after opening the individual packing.
• Do not reuse, it may cause bacterial infection to the patient.
• Ensure the catheter is not used beyond its expiration date.

MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.

Cautions:
- Do not use if package is damaged.
- Do not use if protective caps are loose or missing.
- Discard after single use.
- Do not clean or re-sterilize.
- Do not expose to heat or direct sunlight.
- The product should be used immediately after opening the packaging.

Limitations:
- Single-use only.
- Material/Chemical Compatibility.
- Flow/Pressure Limitations.

Potential Side Effects:
- Mild redness, swelling, or discomfort may occur at or near the vascular access site due to manipulation or movement of the connected extension line.
- Hypersensitivity reactions may occur in patients sensitive to the raw materials used in the Pressure Monitoring Line.

Disposable instructions:
Used Devices may be contaminated with infectious and/or other hazardous materials. Unused expired devices should be disposed of as per local regulations.

Duration of use:
Short-term duration (Normally intended for continuous use for between 60 minutes and 30 days) *[Note: Generally, to be used for up to 72 hours for best performance].*

Storage Conditions:
Store in a Cool & Dry Place.
Keep away from sunlight.
Temperature: +10°C to +40°C.

Shelf life:
5 Years.

Type of Sterilization:
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 devices.

Notice to Users and/ or Patients:
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.

Explanation of symbols used:

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)	CE 0123	CE Mark (CE Marking with Notified Body Number)
	Caution (To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.)		Manufacturer (Indicates the medical device manufacturer) Manufacturing Unit: 525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India. Contact Details.: +91 8527589990 Fax No.: 0124 404 7533 Email ID: info@maisindia.com Website:www.maisindia.com
STERILE EO	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)	REF	Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)
STERILE EO	Single sterile barrier system (Indicates a single sterile barrier system)	LOT	Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)		Date of manufacture (Indicates the date when the medical device was manufactured)
	Do not re-use (Indicates a medical device that is intended for one single use only)		Use-by date (Indicates the date after which the medical device is not to be used)
	Keep dry (Indicates a medical device that needs to be protected from moisture)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
LATEX	Latex free (Indicates a medical device that is Latex free)	DEHP	Indicates product that does not contain the phthalate plasticizers DEHP.
UDI	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)	MD	Medical device (Indicates the item is a medical device)

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Do not use if packaging is damaged and consult instructions for use. (Indicates a medical device that should not be used if its packaging has been damaged or opened, and that the user should consult the instructions for use for additional information)	EU REP	Authorized representative in the European Union / European Community (Indicates the authorized representative in the European Union / European Community OBELIS S.A. Boulevard Général Wahis 53, 1030 Brussels, Belgium Contact Number: +32(2)73 25 954 Email ID: regulatory@obelis.net Website: www.obelis.net
	Non-pyrogenic (Indicates a medical device that is non- pyrogenic)	IN	Country of manufacture (To identify the country of manufacture of products)
10°c 40°c	Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed.		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)
	This way up		

CE 0123

EU REP **Obelis S.A.**
Boulevard Général Wahis 53, 1030 Brussels, Belgium.

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