

INSTRUCTIONS FOR USE

MAIS EX LINE™

Fluid Delivery Tube/Extension Line (Low Pressure)

Description: Extension Line/tube which has flexible tubing that incorporated between infusion line and indwelling Venipuncture device.

Intended Use:

Extension line is a device to be incorporated between infusion line and the indwelling Venipuncture device to minimize the disturbance at cannulation/insertion sites by taking the movement away from cancellation/insertion site. Luer lock and threaded female ports are provided to facilitate safe and sure connection to the Luers.

Indications:

- Extension line is intended to be used for fluid flow directional control.
- It is connected to any system for delivery of two fluids or drugs simultaneously or intermittently.
- This Device can be used as an accessory of administration set/or other devices as per requirement.

Contra Indication:-

- Product should not be used in patients with known Hypersensitivity to any of the materials used.
- Product not to be used with Photosensitive and Chemotherapy Drugs.
- The device is not suitable for use with infant and pregnant women if device label does not claimed DEHP-free.
- If "DEHP Free" is not claimed on the unit pack of device it means, the device should not be considered as Phthalates free during intended use.

Instructions for use:

- Carefully inspect package for integrity and expiry and then remove product from package.
- Peel open the pouch.
- Unscrew the protective cap of female luer.
- Connect male portion of I.V. Set/bag with female luer.
- Remove protective cap of male luer of tubing.
- Hold male luer of tubing upright and open clamp of administration set / bag and allow the solution to displace air entirely from tubing.
- Close Clamp.
- Close flow regulator.
- Connect male luer of tubing to venipuncture device.
- Ensure that all connections are secure.

Materials Used:

PVC, Polyethylene, Polycarbonate.

Medical Conditions:

- The use of the product is restricted to a qualified doctor or a paramedic staff.
- To read "instruction for use" carefully before use of the product.

Warnings:

- 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.
- Use the product immediately after opening the individual packing.
- Use ONLY standard Luer connection devices; non-standard connectors can damage the product.
- Do not recycle, clean or resterile.
- MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.

Cautions:

- Do not use if package is damaged.
- Discard after single use.

Target Age Group:

For All age groups

Duration of Contact of Device :

up to 72 hours for best Performance.

Storage condition: Store at a temperature between +10°C and +40°C, with humidity between 40% and 60%, in a dry place away from direct sunlight.

Device Life: 05 Years

Symbols Used:


	CE Notified Body No.		Keep Away From Sunlight		Non-Pyrogenic
	Catalogue Number		Keep Dry		Latex Free
	Lot No./ Batch No.		Caution		Do Not Reuse
	Manufacturer		Do Not Use If Package is Damaged		Do Not Resterilize
	Date of Manufacturing		Sterilized By Ethylene Oxide		Medical Device
	Use By / Expiry Date		Authorised Representative In The European Union		Unique Device Identifier
	Consult Instructions for Use		Single Sterile Barrier System		Phthalates Free
	Temperature limitation (between +10°C and +40°C)		Country of manufacture		Contain Phthalates

Manufactured by:
Mais India Medical Devices Pvt. Ltd.
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Mfg. Lic. No.:MFG/MD/2019/000037

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CE 0123

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MAIS INDIA MEDICAL DEVICES PVT. LTD. 525-P SECTOR-37, PACE CITY II, GURGAON, HARYANA-122001 (INDIA)				Rev. 01 : The humidity limitation symbol has been removed and EC-REP has been changed to EU-REP.				