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Romsons®

PM-O-LINE®

(High Pressure, Small Bore Extension Line With Male To Female Luer Lock Connectors)

REF GS-3036



INSTRUCTIONS FOR USE

Caution : Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions. Failure to do so may result in complications. To be administered by an expert qualified medical professional. This device is Sterile & Ready for Use. Sterility is guaranteed - if pack is undamaged. The device is for Single Use Only.

Device Description : Small bore high pressure extension line. Suitable for high pressure monitoring and for connection between syringe pump and patient. Provided with male luer lock at one end and female luer lock at other end with protector caps. Connectors fit all standard equipment. Luer lock connectors provide secure fitting. For instant identification of multiple lines, four pairs of different colours stickers (Blue, Red, Yellow & White) are provided.

Population of Use : Adult & Paediatrics.

Intended Use: It is a single use device, used for administration of intravenous fluids in critical care for low prime volume high pressure applications. Intended for use in conjunction with syringe pump to administer controlled intravenous infusions. Also intended for use as accessory for pressure monitoring. For instant identification of multiple lines, four pairs of different colours stickers are provided.

Contents : Sterile, PM-O-Line is packed in soft peel open blister pack.

Size: 50, 100, 150, 200cm.

Material of Construction: PVC, PP, ABS, MB.

Storage: Store in a cool & dry place. (Store between 10°C ~ 40°C).

Indications: Intravenous line administration for very low prime volumes or low dead space applications, for continuous / intermittent timed pressure infusion aided by syringe pump & also used as an accessory for pressure monitoring, etc.

Contra-indications: Not to be used with light sensitive medications, corrosive medications, highly osmolality medications.

Potential Complications / Risks: Vascular air embolism, infection, accidental dislodgement, leakage, blockage, kinking, hole in tube, breakage of tube, tube-distortion, cracking, etc.

Warnings: This device is intended for Single use only.

DO NOT re-sterilize and /or reuse the device, as this can compromise the device performance (functionality) and may cause inadequacy, deterioration of the device technical factor, rendering the device non-functional and unfit for intended use and also this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing.

Re-use of single use device creates a potential risk for patient or use. It may lead to contamination and/or impairment of functional capability.

Contamination and / or limited functionality of the device may lead to injury, illness of the patient.

Precautions :

- Check the integrity of the individual sterilized pack of Device, before use. Do not use if pack is damaged.
- Check the patency of the PM-O-Line. Check 6% luer fitment with combination devices.
- Avoid introduction of air bubbles to prevent air embolism.
- Dispose the device & its accessories after single use as bio-medical waste as per applicable laws.
- Do not Resterilize. Do not Re-use. Discard after single use.

Adverse Events : Air-embolism, hypersensitivity to device material, accidental dislodgement, etc.

General Instructions: To be administered by an expert qualified medical professional. Use maximal sterile barrier precautions during administration. (These are only the guidelines & hence, user's medical experience / expertise is important).

Use Instructions :

- Suitable as line extension for low volume high pressure intravenous fluid applications & also used as an accessory for pressure monitoring.
- Check the packing carefully, if packing is found damaged, torn or pierced, discard the piece.
- Wash-up hands. Use sterile gloves. Peel open the pack & remove the device aseptically.
- Check the integrity / patency of the device. Check for protective caps.
- Remove the male luer lock cap from the male fitting end. Also remove corresponding female luer lock cap from the female luer lock.
- Mount the PM-O-Line on to the incoming intravenous line & prime for air removal or prime with normal saline as per case by appropriate fixation, thus preventing any chance of air embolism.
- Now attach the male luer lock port on to the corresponding attachment. Restore / Open & run the fluid / infusion.
- Use the 4 pairs of coloured stickers provided in the pack for marking / identification of different lines.
- Follow the above procedure in case of additional / simultaneous, running of fluid / infusion line.

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Manufactured by :
Romsons International (Unit-II),
59 J(C), Noida Special Economic Zone,
Noida Dadri Road, Phase-II, NOIDA-201305 (INDIA)

EC REP

OBELIS S.A

Bd. Général Wahis, 53, 1030 Brussels, Belgium

E-mail: mail@obelis.net,

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GRAPHICAL SYMBOLS FOR MEDICAL DEVICE LABELING

STERILE	EO Sterilized Using Ethylene Oxide		Do Not Use if Pack is Damaged
	Pyrogen Free (Non-pyrogenic)		Keep away from Sunlight
	Do not Reuse		Keep Dry
	Do Not Re-sterilize		Consult Instructions for Use
REF	Catalogue Number		Use By
	Manufacturer		Date of Manufacture
EC REP	Authorized Representative in the European Community		Batch Code
	Temperature Limitation (Store between 10°C - 40°C)		Caution, Consult Documents