

INSTRUCTIONS FOR USE

MAISTROL™ IV Administration Set with Flow Regulator

Intended Use:

IV Infusion set is used to administrate the fluids from a container to a patient's vascular system, through a needle or catheter inserted into a vein under gravity feed and medical application in order to ensure their compatibility for infusion solution.

Materials Used:

PVC, ABS, PC, PP, Stainless Steel, Isoprene, PE, Acrylic Copolymer Membrane (Acrylic Copolymer Membrane to be used for Vented Spike)

Indication: For intravascular supply of medication and/or saline.

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:

- Check the integrity of the product. Packaging should be properly packaged.
- Remove the IV Set with Flow Regulator from package using aseptic technique.
- Connect the IV Set with Flow Regulator with the IV Infusion fluid container.
- To achieve the required flow, the flow of regulator to be set as per requirement.
- Please ensure that the regulator of infusion set should be in off position, during the changing of infusion fluid container.

- After completion of infusion, hold the gauze down without applying pressure.
- Discard IV Set with Flow Regulator after use.
- Single use only, do not re-sterilize.

Medical condition:

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

Warnings:

- The product should not be reprocessed.
- Improper transport and handling may cause structural and/or functional damage to device or packaging.
- The product is non-toxic, sterile & non-pyrogenic.
- Do not Clean or resterilize. For single use only. Discard after use.
- Do not expose to heat or direct sunlight.
- The product should be used immediately after opening the packaging.
- **MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.**

Caution:

- Never try to reinsert a partially or completely withdrawn needle.
- 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, in a dry place and away from sunlight.

Device Life: 05 Years

	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		Country of manufacture
	Temperature limit (between +10°C and +40°C)		Contain Phthalates		
	Phthalates Free				

Manufactured by:
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