



INSTRUCTIONS FOR USE

MAISWAY EXTN.TM

Three Way Stopcock with Extension Tube

Description: Three Way Stopcock with extension line is made of medical – grade biocompatible polycarbonate. It's fully transparent body allows visualization of flow of fluid. It is having universal 6% taper on luer which allow connection with a wide variety of standard medical devices.

Intended Use:

Three Way Stopcock with Extension Tube manifold is a device to be incorporated between infusion line and indwelling venipuncture device to deliver additional fluids to the human circulatory system. Extension tube is additionally attached with one end of Three Way Stopcock and another end with infusion line for extension purpose and to minimize the disturbance at insertion site.

Materials Used:

PVC, Polyethylene, Polycarbonate.

Indications:

- Three Way Stopcock with Extension Tube 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.
- If "Lipid Resistant" is not claimed on the unit pack of device it means device should not be considered for lipid drugs during intended use.
- 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.

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.

Instructions for use:

- Carefully inspect package for integrity and expiry and then remove the device from package.
- Connect the female luer of device to the administration set/or other accessories as per requirement.
- Prime the Extension tube before use & expel the air from the tube and close the three way stop cock.
- Connect the male luer of the device to the I.V. access devices e.g. I.V. Catheter.
- Ensure that all connections are secure.
- The moulded arrows on the stopcock handles indicate the open flow paths in relation to the three ports. Turning the stopcock handle to the intermediate position can close all fluid paths.

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 re-sterile.
- 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, in a dry place and away from sunlight.

Device Life: 05 Years

Explanation of symbols used:

	CE Notified Body No.		Country of manufacture		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)		Keep Away From Sunlight		Contain Phthalates

Manufactured by:
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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. Rev.: 02 The word "Remove" was added to the first point (sentence) of the 'Instructions for Use'.			