IFU of Three Way Stopcock

Manufactured by Mais India Medical Devices Pvt. Ltd.

Intended Use:
The Three way Stopcock is a device to be incorporated between infusion line and indwelling venipuncture device to deliver additional fluid to the human circulatory system. Administrate the fluids from a container to a patient's vascular system.

Materials Used:
Lipid Resistance / Non Lipid Resistant Polycarbonate (PC), High-density Polyethylene (HDPE).

Indications:
· Three way stopcock 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 or other devices as per requirement.

Contraindications:
· Product should not be used on patients with known hypersensitivity to any of the material used.
· Product not to be used with Photosensitive and Chemotherapy drugs.
· If "Lipid resistant" is not claimed on the unit pack. It means device should not be considered for lipid drugs during intended use.

Instructions for use:
· Sanitize your hands using an alcohol-based hand cleanser.
· Ensure I.V. line or connecting device (I.V. Cannula, Infusion sets, Extension lines, Syringes, Pressure transducers) are affixed properly and are in function. Prime the Stopcock before use. Ensure that all air bubbles are removed.
· Visually inspect the product packaging to ensure integrity. Do not use if packaging is damaged.
· Open the packaging using aseptic technique.
· The molded arrows on the stopcock handles indicate the open flow paths in relation to the 3 ports.
· Turning the stopcock handle to the intermediate position can close all fluid paths.
· Connect the male luer lock end of the stopcock to the infusion line or any of connecting device.
· Use the rotating tap to direct fluid flow. If bottom channel is closed, the tap will control flow between the two remaining open ports.
· Ensure leak-free and bubble-free fluid administration.
· Monitor the patient and flow throughout the procedure.
· After use, disconnect and discard as per hospital biohazard protocols.

Medical conditions:
· Read the "Instructions for Use" carefully before using the product.
· The use of the product is restricted to a qualified doctor or a paramedic staff.

Warnings:
·The use of this product is restricted to a qualified doctor or a paramedic.
·Read instructions before use.
·MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.
·The product should not be reprocessed.
·Visually inspect and carefully check the product and packaging before use.
·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.
·Re-use of single-use devices creates a potential risk (i.e., infection) of patient or user.
·If the device is reused, then it may cause bacterial infection to the patient, and also may lead to contamination and/or impairment of functional capability which may in turn lead to injury to the patient.
·If there is any change in expected performance of the device or in case of any malfunction the device should be immediately removed & sent back to supplier for analysis.
·Store in a cool & dry place.
·Do not expose to heat or direct sunlight.
·The product should be used immediately after opening the packaging.

Cautions:
·Do not use if the package is Open or damaged.
·Discard after single use.

Target Age Group: Patients of all ages, including neonates, children, adults.

Duration of Contact of Device: Up to 72 Hours for best performance.

Storage conditions: Store at a temperature between +10°C and +40°C, humidity between 40% to 60%, in a dry place and away from sunlight.
Device Life: 05 Years

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)		Latex free (Indicates a medical device that is Latex free)
	Keep away from sunlight (Indicates a medical device that needs protection from light sources)		Date of manufacture (Indicates the date when the medical device was manufactured)
REF	Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)		Keep dry (Indicates a medical device that needs to be protected from moisture)
STERILE EO	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)		Use-by date (Indicates the date after which the medical device is not to be used)

Symbols	Title of the Symbol	Symbols	Title of the Symbol
STERILE EO	Single sterile barrier system (Indicates a single sterile barrier system)	IN	Country of manufacture (To identify the country of manufacture of products)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)	LOT	Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)
	Do not re-use (Indicates a medical device that is intended for one single use only)	CE	CE Mark
	Non-pyrogenic (Indicates a medical device that is non- pyrogenic)	MD	Medical device (Indicates the item is a medical device)
	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
	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
UDI	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)	10°c 40°c	Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed.
40% 60%	Humidity limitation (Indicates the range of humidity 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)
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