3-Way Stopcock

Lipid resistant

INTENDED USE

3-way stopcock is a medical device sterilized using Ethylene Oxide gas and easy visualization to be able identified without opening.

Three ways, two female luer-lock connections and one male. With protective cap.

This product is suitable for lipids, cytostatics, antiseptics and other drugs of high caustic power

COMPOSITION

Polycarbonate body completely transparent. Exempt from latex, PVC and pyrogen

INSTRUCTIONS FOR USE

Recommended use for intravenously infusion and intermittent administration of medications.

- Carefully inspect package for integrity and expiry and then remove stopcock from package.
- Remove caps from luer ends.
- Use the product immediately after opening the individual blister packaging.
- Connect with appropriate site of stopcock with extension tube or other devices as per your requirements.
- Remove any air embolism from stopcock or connected tubes.
- Clean the site of attachment and connect with the patient.

PRODUCT CHARACTERISTICS

Product is sterilized with Ethylene Oxide (ETO) gas as per standardizer and validates sterilization cycle as per ISO 11135.

Compatible with blood and blood products.

Red and blue pegs for arterial and venous line identification.

Pressure tested pneumatically and hydrostatically: 6 bars.

PRECAUTIONS AND RECOMMENDATIONS

Single use.
The use by more than one patient may cause a cross-infection.
Do not use the product if it is polluted, dirty or evidently deteriorated.

STORAGE AND SHELF-LIFE

Keep away from sunlight. Keep dry.
Shelf-life: 5 years.

PRODUCT DIMMENSIONS

REFERENCE	PRODUCT TOTAL (mm)	L FEMALE CONNECTION (mm)	L MALE CONNECTION (mm)
8400020	50x25	11	13

Packaged in unit blister with product description

CONFIGURATION			
REFERENCE	**UNITS BOX**	**MESUREMENTS BOX (cm)**	**WEIGHT BOX* (kg)**
8400020	500 Un. (10 box of 50 un.)	56x30x18	3.87

* TOLERANCES: Weight ± 0.5 Kg

IN COMPLIANCE WITH:

- Directive 93/42/EEC of the Council, Directive 2007/47/EC of the European Parliament and of the Council and Regulation (EU) 2017/745 of the European Parliament and of the Council.
- Class IIA, sterile (according to Annex IX of Directive 93/42 and Annex VIII of Regulation 2017/745).
- Enterprise certified by ISO 13485 and ISO 9001.
- Medical Devices Distributor License No.: 3689-PS.

Sistema de Gestión ISO 9001:2015 ISO 22716:2007
www.tuv.com ID 9105078921

MANUFACTURER:

La-med Healthcare Pvt. Ltd.- INDIA
Enterprise certified by ISO 13485 and in compliance with Directive 93/42/EEC of the Council, Directive 2007/47/EC of the European Parliament.

3-way Stop Cock

INSTRUCTIONS FOR USE :

Scope :
This IFU is applicable to the 3-way stop cock manufactured by La-med Healthcare Pvt. Ltd. Faridabad, Haryana, India.

MATERIALS USED :
Polycarbonate, HDPE

INTENDED USE :
The 3–way stop cock is used for intravenous blood transfusion or the transfusion of blood derivatives and infusion of nutritive or medicinal fluids with the help of I.V. Cannula. With 2 female luer lock connection for the flow path complying ISO 594-2 for infusion of two fluids at a same time.

INDICATIONS :
- Infusion of I V Fluid
- Infusion of I V Drugs administration
- Infusion of bloods, bloods derivative, medications with lipids.

CONTRAINDICATIONS
- Not to be used in patients with known hypersensitivity to any of the materials used.
- Not to be used with photosensitive and Chemotherapy drugs.

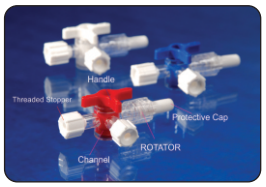
Known Characteristic of Device in case of re-use.
- Due to contaminations any infectious disease can transfer.

INSTRUCTIONS FOR USE

1. Carefully Inspect package for integrity and expiry and then remove stopcock from package.
2. Remove caps from luer ends
3. Use the product immediately after opening the individual blister packing.
4. Connect with appropriate site of stopcock with extension tube or other devices as per your requirements.
5. Remove any air embolism from stopcock or connected tubes
6 Clean the site of attachment & connect with the patient

All End of the 3-way stop cock terminates in a male or female conical fitting according with ISO 594-1, 2 for preferably use with respective device.

WARNINGS
- For single use only
- Read instructions before use.
- Check expiry date prior to use.
- The product should be used according to the instructions for use.
- 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 guarantied non- toxic, sterile & non-pyrogenic if the package has not been opened or damaged.
- Discard after use.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and country laws and regulations.



- Ensure proper disposal of product and packing after use.
- Use the product immediately after opening the individual packing.
- The product should not be reprocessed.
- The product should be used by a doctor/ Registered practitioner or Paramedic.
- Store in a cool and dry place.
- Protect from excessive heat or direct sunlight.

Cautions :
- Do not use if protective caps are detached.
- Do not use if package is damaged.
- Discard the set after single use.

Disposable System :
Dispose off the product in accordance with accepted medical practice and applicable local, state and country laws and regulations.

Target Age Group :
For all age groups.

Duration of Use : 24 hours

Storage Condition: Cool & dry Place

Device Life : 05 Years

Non- Pyrogenic

Single Use. Do Not Reuse.

Do not Resterilize.

Protect from direct sun light.

Keep Dry.

Do not use if package is damaged.

STERILE EO Sterilized by Ethylene Oxide.

Consult the IFU

REF Manufacturer's Catalouge Number

LOT Indicated the manufacturer's batch code so that the batch or lot can be identified.

Indicated the date when the medical device was manufactured.

Indicated the date after which the medical device is not to be used.

Indicated the medical device manufacturer.

EC REP Indicated the authorized representative in the European Community.

CE 2460 Symbols of conformity with notified body

La-med® CONSCIOUS CARING

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