



TECHNICAL DATA SHEET 3-Way Stopcock

DESCRIPTION: Product **3-Way Stopcock** is a Class IIa medical device that is used in conjunction with an infusion and/or venous access device to administrate intravenous fluids.



PRODUCT VARIANTS:

Following variants are available for the product Three-Way Stopcock :

- Blue, Red **OR** White Tap
- Packed in Rigid **OR** soft blister unit packing*
- With color identification **PEG**
- Click at every 45° rotation

*Bulk (unpacked) product is also available; Blister with Tyvek also available for Product.

Specification and Packing Details for Three-Way Stopcock:

Flow Rate in ml/min	Color of Tap	Inner Packing	Outer Packing
525 ± 10%	Blue, Red, White	50 Pcs	500 Pcs

PRODUCT CHARACTERISTICS:

- The device **3-Way stopcock** is designed to provide an additional port for infusion and/or bolus injection between the infusion line and the venous access.
- The body of the stop cock has a smooth and regular bore, designed to allow maximum fluid flow without any turbulence or formation of air bubbles, even at high pressure.
- The device **3 Way Stop Cock** has a fully transparent polycarbonate body for easy visualization of flow. The device is also available in lipid-resistant transparent material for administration of lipid-containing IV fluids.
- The device **3-Way Stopcock** has two female connectors and one male connector with universal 6% taper (as per ISO-594). The device may be used as a protective stopper for any standard female and/or male Luer.
- The device is leak-proof up to **5 bar (72.5 psi)**
- The device **3-Way Stopcock** has a uniform and fixed dead space for accurate drug administration.
- Smooth rotation of the tap over 360° is possible using single-hand operation.

- The product **3-Way Stopcock** is designed and manufactured to ensure smooth flow of blood at high pressures.
- The device **3-Way Stopcock** is designed for Smooth and jerk-free operation with arrow Indication Marks to indicate the direction of Flow.
- The device **3-Way Stopcock** does not compromise the clinical condition or the safety of patients and minimizes mechanical stress and intimal injury to blood vessel.
- The device **3-Way Stopcock** is to be used in ambient conditions and should be used **ONLY** by a qualified doctor or a paramedic.

RECOMMENDED MAXIMUM TIME OF USE: 96 hrs as per CDC guidelines

MATERIAL COMPOSITION:

COMPONENT	MATERIAL
Body 3-Way Stopcock	Lipid resistant PC (Polycarbonate)
Tap	HDPE
Threaded Stopper	HDPE
Rotator	PC (Polycarbonate)
Plain Stopper	PP (Polypropylene)

PACKAGING MATERIAL:

ITEM	MATERIAL
Individual Sterile Packing (Blister)	Soft PP/PE OR Rigid PVC film, and Medical Kraft Paper 60/70 GSM OR Tyvek
Inner Carton (50)	Duplex Board
Master Carton (500)	Kraft-Pulp Paper

Labels conform to requirements of EC Medical Device Directive (MDD) 2007/47/EC and international labeling standards.

EXPIRATION/VALIDITY: 5 years from date of manufacturing.

METHOD OF STERILIZATION: Terminal Ethylene Oxide (EtO gas) Sterilization; residual EtO gas within normative limits.

TESTING & ANALYSIS: Testing of sterility, pyrogen content and physical characteristics (leakage testing, flow rate of lumen, packaging integrity, etc.) is performed on each batch before release.

BIOCOMPATIBILITY: The product **3-Way Stopcock** complies with requirements for biocompatibility as per ISO-10993 international standard, based on testing of the finished device

STORAGE: Store in a cool and dry place at room temperature away from moisture, direct sunlight and heat sources.

METHOD OF DISPOSAL: Medical devices and sharps contaminated with blood or other body fluids must be discarded in special containers and disposed off by incineration. Disposal must be in conformity with relevant national/international standards. Please refer to hospital protocols for disposal.

INTENDED USE: The product **3-Way Stopcock** is intended for infusion therapy

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