

PRODUCT SPECIFICATION

PRODUCT NAME : THREE WAY STOPCOCK

Special Features

- For accurate drug administration
- Can withstand the pressure in normal procedures
- Arrow marks on the tap indicate direction of flow
- Leak proof upto three bars of pressure
- Lipid resistance also available
- Available in three colours – Blue, Red & White

Product Information

Material : Regular Polycarbonate OR Lipid-Resistant Polycarbonate Body, HDPE, PP

MATERIAL COMPOSITION

COMPONENT	MATERIAL	GRADE
Body 3-Way Stopcock	PC (Polycarbonate)	1494-T/HPS-7
Tap	HDPE	HD 50MA 180
Threaded Stopper	HDPE	HD 50MA 180
Rotator	PC (Polycarbonate)	PC 144R
Plain Stopper	PP (Poly-Propylene)	H 110MA

Colour : Transparent body with Blue, Red OR White Tap

Sterilization : Sterilized by Ethylene Oxide Gas

Labeling : Shall comply with the corresponding labeling specification and customer requirement.

Shelf Life : 5 years from the date of manufacture

Storage condition and : Shall be stored in cool dry place at room temperature away from moisture, direct light heat sources.

PRODUCT VARIANTS:

- With OR without extension tubing
- Packed in Rigid OR Soft Blister unit packing*
- Bulk-packed product
- Blister with Tyvek

Packing Details for three-Way Stop Cock:

Flow Rate in ml/min	Inner Packing	Outer Packing	20' Container	40' Container
525 ± 10%	50 Pcs	500 Pcs	5,00,00 Pcs (1000 Cartons)	12,14,000 Pcs (2428 Cartons)

Certifications : CE
ISO 9001 : 2008
ISO 13485 : 2003

PRODUCT CHARACTERISTICS

- The device 3-Way Stop Cock 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 pressures.
- This 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 Stop Cock has two female connectors and one male connector with universal 6% taper (as per ISO-594). Thus the device may be used as a protective stopper for any standard female and/or male luer
- The device is leak-proof up to 3 bar (43.5 psi).
- The device 3-Way Stop Cock 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 device is designed for smooth and jerk-free operation with arrow Indication marks to indicate the direction of flow.
- The device does not compromise the clinical condition or the safety of patient and minimizes mechanical stress and intimal injury to blood vessels.
- The device 3-Way Stop Cock is to be used in ambient conditions and should be used ONLY by a qualified physician, nurse or paramedic.

RECOMMENDED MAXIMUM TIME OF USE: 96 hrs

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

Directions for Use:

1.1 Indications

- To deliver simultaneous infusion of two different IV fluids
- To administer bolus IV injections through existing access site for IV infusion
- To take blood samples through existing IV access site, without a second venipuncture
- For needle-free access in high-risk patients

1.2 Contraindications

- Product should not be used in patients with known hypersensitivity to any of the materials used
- Administration of highly viscous fluids
- NOT to be used for blood transfusion.

1.3 Instruction for Use

ATTACHMENT of THREE-WAY STOP COCK to IV ACCESS

- Ensure that venous access (e.g. IV cannula) is patent by flushing with saline.
- Inspect packing of 3-way Stop Cock visually to ascertain that package is intact
- Remove the Stop Cock from sterile packing taking care to maintain sterility
- Connect one or two IV Infusion lines to the ports as required
- Remove protector from male portion of stop cock and hold it upright
- Open clamps of IV infusion lines and displace air entirely by rotating the tap to open position (all 3 flow directions should be open)
- Rotate the tap to closed position (output from stop cock is closed)
- Connect it to venous access device (e.g. IV cannula) and secure the connection with rotating transparent lock
- Rotate the tap to open position and adjust the flow of infusion fluid

REMOVAL OF 3-WAY STOP-COCK

- Rotate the tap to closed position such that connection with IV access is terminated.
- Clamp input IV infusion lines.
- Keep injection stopper ready for closing IV access (e.g. IV cannula) after removal.
- Unscrew the transparent rotator lock and remove 3-way stop cock; close IV access with injection stopper or other device.
- Discard the used stop cock according to your facility's standard practice.

1.4 Cautions for Use

- The use of this product is restricted to a qualified doctor or a paramedic.
- Read instructions before use
- The product should be used according to the instructions for 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 guaranteed sterile & non pyrogenic if the package has not been opened or damaged.
- Do not clean or resterilise. For Single use only. Discard after use.

1.5 Expiration Date

The shelf life of the gloves is 5 years from the date of manufacture.