

IFU of 3 Way Stop Cock (with/ without Extension Tube) manufactured by Chiron Surgimed Pvt. Ltd.

General Device Description: Three Way Stop Cock manufactured from transparent polycarbonate/ PP/ HDPE/ ABS/HPDE + Master Batch/ PVC. Inside is completely smooth & available with molded luer lock. It is manufactured from non-toxic medical grade material. Three Way Stop Cock is E.T.O. sterile and pyrogen free.

Product Name: Three Way Stop cock (with/ without Extension Tube)

Brand Names: Chiro-Way, Chiro-Way Line

Variants:

1. Three Way Stop Cock (Lipid/ Non-Lipid)
2. Three Way Stop Cock with Extension Tube

Intended use:

3 –way stop cock is intended for fluid flow directional control and for providing an access port for the administration of the solution, withdrawal of fluid, and pressure monitoring, with the help of I.V. Cannula. With 2 female luer lock connection for the flow path complying ISO 80369-7 for infusion of two fluids at a same time.

Material of construction:

Component	Material
Handle	HDPE + Master batch
3 way Body	Poly carbonate
White Cap	Polypropylene
Rotator Male Luer Lock	Poly carbonate
Threaded Stopper	High density poly ethylene
Extension Tube	PVC (phthalate free)
Male conical fitting	MABS

Intended Medical Indication:

- Infusion of IV Fluid
- Infusion of IV Drugs administration

- To deliver the fluid in the patient who are unable to take orally

Contraindications:

- Not to be used in patients with known hypersensitivity to any of the materials used.
- Not to be used with Lipids if non lipid stop cock used.
- Not to be used with highly viscous fluids.
- Not to be used with photosensitive and Chemotherapy drugs

Known Characteristics of Device in case of re-use:

- Contamination may cause any infectious disease

Intended Patient Population:

All age group such as – Neonates, Pediatrics & Adults

Intended User: A qualified doctor or a paramedic

Use Environment: Proper healthcare set up

Instructions for Use:

- Select the suitable variants of Three Way Stop Cock such as lipid and non-lipid types.
- 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 packing.
- 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 & connect with the patient.

Intended Clinical Benefits to the Patients:

- Infusion of IV fluid
- Provides three way access and Enables safe and fast administration.
- A 3-way stopcock can be used on intravenous (IV) tubing to turn off one solution and turn on another and its rotating male luer makes the 3-way stopcock convenient to connect with other accessories. It is open to the air without a membrane when cover is not in place, and for that reason is considered an open IV system.

Performance Characteristics:

- Administration of fluids depends on the size of the catheter chosen and the flow of the fluids will be more in larger diameter catheter.
- Infuses more than one fluid at a single time. By connecting one or two I.V. Infusion lines as required to the ports, male portion protector was removed & hold it upright.
- Open clamps of I.V. Infusion lines & displace air entirely by rotating the tap to open position.

Accessories which can be used with the device:

- Three Way Stop Cock (with/ without extension tube) does not have any accessories provided along with this device. But it is usually combined with IV cannula and other infusion system which are widely available in market.

Warnings:

- For single use only
- 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 which leads to leakage of administered fluids or drugs.
- The product is guaranteed non- toxic, sterile & non- pyrogenic if the package has not been opened or damaged. Don't use the product if package is damaged.
- 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.

Limitations:

- Three way stop cock reduce flow rate precision during multiple fluid administration.
- Lipids stop cock not to be used with non-lipid stop cock used..

Potential Side Effects:

- Hypersensitivity to the material used
- Re-use/ Contamination may cause any infectious disease.

Disposing instructions:

Discard in proper waste container & dispose off the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste, as improper disposal can lead to bio-hazard.

Return of Device:

The return of defective device should be carried out within a week of receipt of the product along with the evidence or damaged product and the product should not have been used under any circumstances, at any condition.

Duration of Use:

72 hours (It is recommended to remove the Three way stop cock (with/without extension tube) after 72 hours from the patient. The user is accountable for any type of problem taking place in case of use after 72 hours of the same device.)

Storage Condition:

Temperature: 05-45°C and Humidity: 60±5%

Keep away from sunlight and keep in dry condition.

Shelf Life of the Device:

05 Years

Type of Sterilization:

This device is supplied as sterile by using ETO Sterilization.

Notice to Users and/or Patients:







In the event of malfunction of the device or changes in its performance that may affect safety, or any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.













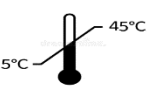
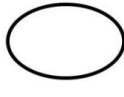

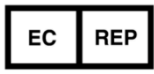
How device is supplied:




Three way stop cock (with/ without extension tube) is packed 1 unit/piece in P.V.C. hard film for blister packaging and medical grade for paper pouch packaging.

Name	Units per Box (Secondary packaging)	Units per Box (Tertiary packaging)
3 way stop cock (Lipid/ Non-Lipid Resistant)	50 Pcs/box	500 Pcs/carton
3 way stop cock (with Extension Tube)	50 Pcs/box	600 Pcs/carton

Explanation of Symbols used:

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Medical device (Indicates the item is a medical device)		Latex free (Indicates a medical device that is Latexfree)
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)		Date of manufacture (Indicates the date when the medical device was manufactured)
	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.)		Use-by date (Indicates the date after which the medical device is not to be used)

	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)		Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)		Batch code (Indicates the manufacturer's batch code 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)		Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)
	Non-pyrogenic (Indicates a medical device that is non-pyrogenic)		Country of manufacture (To identify the country of manufacture of products)
	Do not use if package is damaged and consult instructions for use (Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information)		CE Mark
	Humidity limitation (Indicates the range of humidity to which the medical device can be safely exposed)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed.)		Single sterile barrier system (Indicates a Barrier single sterile system)
	Keep dry (Indicates a medical device that needs to be protected from moisture)		Authorized representative in the European Community / European Union (Indicates the authorized representative in the European Community / European Union)

			CMC Medical Devices & Drugs S.L.C/ Horacio Lengo, N°18, CP 29006, Málaga-Spain Tel: +34951214054; Email: info@cmcmedicaldevices.com
	DEHP and Phthalate Free (Indicates a medical device that is DEHP free) Note: Applicable only for Three Way Stop Cock (Lipid/Non-Lipid) with Extension Tube		Refer to instruction manual/booklet
	Manufacturer (Indicates the medical device manufacturer) Chiron Surgimed Pvt. Ltd. Survey No. 883/1, GIDC Road No. 3, Mansa-382845, Dist. Gandhinagar, Gujarat Contact No. : +91-8735918291 Email : info@chironsurgimed.com Website : www.chironsurgimed.com		

REVISION HISTORY:

Sr. No.	Document Name	Document No.	Issue No.	Issue Date	Revision No.	Revision Date	Reason for Amendments
1.	Instruction for Use	CSL/IFU/3 WSC/00	01	01.10.2024	00	--	Initial Issue