INSTRUCTION FOR USE FOR THREE WAY STOP COCK

Product Name	:	**Three Way Stop Cock**
Brand Name	:	ULTRAMED ULTRAWAY THREE WAY STOP COCK
Manufacturer's Name	:	Ultra for medical products (Ultramed) Co (U.M.I.C) S.A.E
Manufacturer's Address	:	Part No. (304:310) & part no. (312) – Industrial Area, Arab El Awamer – Abnoub - Assiut – Egypt.

Description of the Device:

- The 3-way stopcock is a short-term medical device that has been used for many years under various brands and is designed to provide controlled access to the IV cannula system for the intravenous administration of fluids and medications. As part of the Stopcock family, it enables the simultaneous or sequential delivery of two fluids or drugs at the same time. The device features are two female luer ports and one male luer port, allowing connection between the infusion line and venous access for infusion and/or bolus injection. The components are manufactured from biocompatible polycarbonate and polyethylene materials that are widely used in hospitals and clinical settings.
- Uniform smooth bore throughout permits maximum infusion flow and prevents turbulence as well as formation of air bubbles.
- The Product is manufactured from DEHP-free, latex-free & non-toxic medical grade Polycarbonate, Polyethylene & Polypropylene.
- 3-way Stopcock is leak-proof up to 4.5 bar (65 psi).
- Approximate Priming volume in three way stop cock is 0.23 ml.
- The device is also available in lipid-resistant transparent material for administration of lipid containing IV fluids
- Based on the application and requirements, various features are incorporated in the Three Way Stop Cocks design as follows:
- Rotating luer lock and threaded female ports facilitates safe and secure connection to Luer of other systems.
- Arrow indication marks on the handle to indicate the direction of flow.
- Smooth rotation of the tap over 360° is possible using single-hand operation
- The 3 Way Stop Cock has a fully transparent polycarbonate body for easy visualization of flow.
- The 3-way stopcock complies with the applicable requirements of **ISO 8536-10:2015**
- Male and female fitting of device are provided with 6% luer taper for leak proof connection with other devices as per EN ISO 80369-7:2021, ISO 80369-1:2018 & ISO 80369-20:2015.
- It is also available to be produced as 3-Way with Extension tube which is made from biocompatible medical grade PVC material and available in DEHP Free PVC tubing.
- The 3-Way Stopcock has a uniform and fixed dead space for accurate drug administration.
- The 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 product is sterilized using EO (Ethylene Oxide) gas.
- Its packing is made of medical paper and blister film.
- The product and packaging don't contain any constituent of animal origin.
- The maximum duration of use is not more than **3 days (72 hours)** for best performance**.**
- The maximum duration of use of the three-way stopcock shall not exceed **24 hours** when used for parenteral nutrition or lipid emulsions, and **12 hours** when used with propofol solutions.

- This product is for single use.

Material Used:

- HDPE [High Density polyethylene].
- PC [Polycarbonate].
- PP [Polypropylene]

Intended purpose:

The product is used to deliver Intravenous fluid and medicines into human circulating system to maintain hydration and/ or correct dehydration in patients who are unable to take sufficient volume of oral fluids. The Three Way Stop Cock family is designed to provide access into IV Cannula system for administration of two fluids or drugs at the same time.

Variants:

Trade Name	REF (Product ID Number)
ULTRAMED ULTRAWAY Three Way Stopcock	1006
ULTRAMED ULTRAWAY Three Way Stopcock (Lipid Resistant)	1006L

Clinical Indications:

- To deliver Intravenous fluid and medicines in to human circulating system.
- To maintain hydration and/or correct dehydration in patients who are unable to take sufficient volume of oral fluids.
- To provide access into IV Cannula system or infusion administration set for administration of two fluids or drugs at a time

Contraindications:

- Do not use in patient with a known hypersensitivity to any of the product components
- Do not use the stopcock for purposes other than its intended use
- Avoid in scenarios where the stopcock may be exposed to excessive pressure beyond its rated capacity
- Do not use with Photosensitive and Chemotherapy drugs
- Do not use with blood transfusion

Device Limitation:

- Do not use for the administration of highly viscous fluids.
- Do not use for the administration of Blood.
- Do not use with Photosensitive and Chemotherapy drugs
- Do not use with pressure upper than 4.5 bar (65 psi)

Patient Target Group:

- No specific requirements or restrictions on use for patient population or user group.
- Adult & Pediatrics.
- It used for male and female patients (all Ages).
- Patients that admitted to intensive care units and Emergency Rooms, and rarely, those requiring IV infusion on outpatient basis.

Intended User:

To be used by an expert qualified medical professional, Skilled or Trained Personnel ***(In-Charge)***

Application site in the body:

- The medical device Three Way Stopcock is in-direct contact with patients' blood.
- Intravenous route.

Replacement Frequency:

- Change the device immediately upon suspected contamination or if the integrity of the system is compromised (e.g., leakage, disconnection, or damage).
- The maximum duration of use is not more than **3 days (72 hours)** for best performance
- The maximum duration of use of the three-way stopcock shall not exceed **24 hours** when used for parenteral nutrition or lipid emulsions, and **12 hours** when used with propofol solutions

Clinical benefits:

- The clinical benefits derived from the device are achieved indirectly. The device itself helps in establishment of conduit for venous access into vein for administration of two or more fluids at the same time such as solutions, parenteral nutrition, medicines and to maintain hydration in patients who are unable to take sufficient volume of oral fluids.
- For infusion of more than one fluid at a single time.
- Used to direct the flow of fluid through an infusion system, while allowing multiple fluids to be connected. It consists of three ports, each of which can be opened or closed independently.
- Used to deliver Intravenous fluid and medicines into human circulating system.
- To maintain hydration and/ or correct dehydration in patients who are unable to take sufficient volume of oral fluids.
- To provide access into IV Cannula system for administration of two fluids or drugs at the same time.

Use Environment:

Intended for use in healthcare settings where aseptic technique can be maintained, including Hospital, Emergency Room, Critical care room, intensive care units and other clinical areas where intravenous therapy is administered and rarely, those requiring IV infusion on outpatient basis but under the supervision of qualified healthcare personnel

Life time of device:

The device is intended for **short-term use only**, with a maximum continuous use period of **72 hours (3 days)**.

When used with parenteral nutrition or lipid emulsions, the maximum duration of use is **24 hours,** when used with propofol solutions, the maximum duration of use is **12 hours**

Sterility status and Method of sterilization:

Three-way stopcock supplied in sterile state and sterilized using Ethylene oxide**.**

Information on medical device intended to be used with other devices:

The Three-Way Stopcock is equipped with a male fitting incorporating a rotatable threaded locking collar to ensure secure connection to an I.V. cannula. It also features dual female fittings with a 6% taper, intended for connection to an extension tube, another Three-Way Stopcock, or an IV infusion set. The male and female fittings comply with the applicable requirements of EN ISO 80369-7:2021 (Luer connectors for intravascular or hypodermic applications), EN ISO 80369-1:2018 (General requirements for small-bore connectors), and EN ISO 80369-20:2015 (Test methods)

Performance Characteristics:

- **Rotating luer lock** and threaded female ports facilitates safe and secure connection to Luer of other systems as EN ISO 80369-7:2021, EN ISO 80369-1:2018& EN ISO 80369-20:2015.
- **Arrow indication marks** on the handle to help identify the direction of flow. Clear visual indicators can make configuration easier to understand during setup.
- **Handle** allow **360°** Smooth rotations, allowing the user to adjust the flow configuration according to the intended setup. This provides flexibility when managing the connected pathways.
- **Transparent base of channel** facilitates observation of flow.

- A **sterile cap** is attached to the lumen when the extra ports are not connected to an administration set or syringe.
- Uniform smooth bore throughout permits maximum infusion flow and prevents turbulence as well as formation of air bubbles.
- The Product is manufactured from **DEHP-free, latex-free & non-toxic** medical grade Polycarbonate, Polyethylene & Polypropylene
- For pressure up to **4.5 bar (65 psi)**
- The product is available in **lipid-resistant** and **non-lipid-resistant** versions; this provides configuration options for different intended applications. The appropriate version should always be selected according to fluid compatibility and the manufacturer's product information.

Risks Associated with reuse

Re-use of the device may create a potential risk to the patient, including contamination and/or impairment of the device function.

Instruction for Use:

	Ultraway three Way Stopcock Action	Rational
	Before Using Ultraway three Way Stopcock	
1	Confirm Fluid Compatibility	to verify whether the stopcock is compatible with the fluids being used. If lipid-containing fluids are involved, use a lipid-resistant version according to the manufacturer's recommendations
2	Establish need for Ultraway three Way Stopcock.	A Ultraway three Way Stopcock is a medical device that is used for simultaneous and continuous infusion of two fluids and control flow direction
3	Explain to patient you are going to use Ultraway three -Way Stopcock for him.	To reassure patient during procedure.
4 5 6	Perform hand hygiene and use appropriate PPE in accordance with the healthcare facility's aseptic procedures	This prevents the transmission of microorganisms.  To reduce risk of infection. Using gloves decreases the transfer of microorganisms. 
7	Raise bed to a comfortable working height.	This helps prevent biomechanical injury to the health care provider.

	Ultraway three Way Stopcock Action	Rational
8	Inspect Three Way Stop Cock package for integrity and expiry and then remove from package.	To ensure the sterility of the product.
9	Flush the system, rotate the stopcock to allow a saline flush or another appropriate solution to pass through the line	To clear any blockages or maintain patency.
During Use		
10	Connect I.V. Infusion set to both female parts of Three Way Stop Cock after removing luer Lock Plug.	To set up infusion therapy
11	Open the roller clamp of IV Sets. Expel the air from the PVC (DEHP Free) tube and close roller clamp	To ensure air expel
12	Remove Luer Lock Plug of I.V. Cannula and insert male part of Three Way Stop Cock into female part of I.V. Cannula.	To start the infusion process for delivery of two fluids or drugs at a time.
13	Confirm that the stopcock is correctly connected to the IV line, the medication source, and the flush or vent line.	To ensure proper fluid direction, maintain sterility, prevent air entry or leakage, and promote safe and accurate therapy delivery.
14	To switch between fluids or medications, rotate the stopcock handle to the appropriate position	To allow for a smooth transition between different fluids or treatments.
15	To administer more than two drugs or fluids,	Connect two or more of the three-way stopcock with each other.
16	Regulate the flow by adjusting roller clamp to achieve desired flow rate.	To achieve desired flow rate
17	Rotate the stopcock to control the fluid's flow:	a. To allow fluid to pass through two ports simultaneously, set the stopcock so that both ports are open. b. To shut off one pathway, rotate the handle so that one of the ports is closed off.
18	Monitor the Flow: After adjusting the stopcock, check the system.	To ensure that the fluid is flowing through the correct pathway. This may involve checking the pressure, flow rate, or observing the fluid's behavior.
After Use of Ultraway three Way Stopcock		
19	Perform hand hygiene.	This reduces the transmission of microorganisms.

	Ultraway three Way Stopcock Action	Rational
		
20	When you're finished using the stopcock, rotate the handle to the "off" position.	To stop the flow and prevent any accidental leakage or contamination.
21	Disconnect three -Way Stopcock from iv cannula.	To stop infusion process.
22	Remove gloves and place patient in a comfortable position. Assess patient's level of comfort. Perform hand hygiene.	This promotes patient comfort and reduces the transmission of microorganisms. 

Warnings:

- For single-use only.
- Discard after single use, Reuse may cause cross infection, device malfunction, and patient reactions to endotoxins, since sterilization cannot inactivate toxins released by Gram-negative bacteria even if the bacteria themselves are killed
- Do not re-sterilize and/or reuse as it can compromise device performance, leading to malfunction, reduced functionality, or increased risk of contamination and may cause inadequacy, deterioration of the device technical factors, rendering the device non-functional and unfit for intended use and also this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing
- Re-use of a single-use device creates a significant risk of infection or impaired performance, which may result in patient injury or illness.
- The device should only be used by a qualified doctor or qualified healthcare professionals with appropriate clinical and technical training.
- Ensure the three-way stopcock type is appropriate for the intended fluid to be administered.
- Use lipid-resistant three-way stopcock for administration of lipid-containing solutions. Lipophilic drugs containing lipids can be administered only with lipid resistant type
- Do not use non-lipid-resistant three-way stopcock for lipid-containing solutions. Use of incompatible solutions or inappropriate type may affect device performance or lead to material degradation, cracking, or compromised therapy delivery

- Confirm compatibility of the three-way stopcock with the intended solution or medication prior to use.
- Store up to 30 ℃ ± 2℃, away from direct sunlight, heat, and moisture to avoid product degradation.
- Dispose of the device in accordance with safe biomedical waste disposal protocols.
- Ultramed accepts no responsibility for any incidental or consequential damages caused by reuse of the device.

Precautions:

- Carefully read and follow all instructions prior to use. Failure to do so may result in complications.
- The device is supplied non-toxic, sterile and non-pyrogenic and ready for use. Sterility is guaranteed only if the package is undamaged.
- Do not use if the packaging is opened, damaged, or expired.
- Use the product immediately after opening the individual pack.
- Inspect the device for integrity, sterility, and functionality before use.
- Ensure procedure is conducted under strict aseptic technique.
- Monitor the patient's condition and vital signs during application and use.
- The device is DEHP-free and latex-free, minimizing allergic risks.
- After use, dispose the device as biomedical waste as per facility approved protocol
- Ensure compatibility with tubing to prevent leaks or disconnections.
- Do not use the product if it is dirty or evidently deteriorated.
- Use with caution in patients with increased bleeding tendency. Monitor the vascular access site for signs of bleeding.
- Always confirm the flow of the drug solution after operating the three-way stopcock by visual inspection to transparent polycarbonate main body.
- Some organic solvents, alcoholic disinfectants might cause cracking of the device.
- If "Lipid resistant" is not claimed on the unit pack. It means device should not be considered for lipid drugs during intended use
- When using a low-pressure extension tube with a three-way stopcock, ensure that the compatibility of all connected components is maintained. A lipid-resistant extension tube shall be connected only to a lipid-resistant three-way stopcock, and a non-lipid-resistant extension tube shall be connected only to a non-lipid-resistant three-way stopcock to maintain system compatibility and performance.
- Do not use if protective cap is loose or missing

Potential Complications / Risks:

Risk from improper connection due to a faulty 6% Luer taper; leakage; internal blockage or occlusion of the fluid pathway; cracked, broken, or damaged channel; malfunction of the rotating handle leading to incorrect flow direction; air entry into the line resulting in air embolism; septicemia due to contamination; bacterial contamination resulting from improper handling; particulate contamination; device failure under excessive pressure; and, when the standard 3-way stopcock is used with lipid-containing solutions, material incompatibility may result in degradation, cracking, leakage, or loss of mechanical integrity of the stopcock, potentially leading to interruption or alteration of fluid delivery and contamination of the fluid pathway.

General Instructions:

1. To be used by a trained and qualified healthcare provider and medical professional.

2. During operation, take all necessary sterile barrier precautions. After usage, dispose of the device as biomedical waste in accordance with the applicable laws

Conditions of Handling, Preservation and Storage:

- Not more than 5 cartons on each other.
- Nice Ventilated place.
- Out of Sunlight.
- Suitable temperature up to 30 ℃ ± 2℃.
- Humidity: Up to RH 65% (± 5)

Safe Disposal of single-use medical devices:

- Adopt adequate precautions for the elimination and disposal of the device and comply with the provisions of the laws in force on biologically hazardous waste.
- Single-use devices must be segregated from other reusable devices and, should not be returned to a Decontamination facility for reprocessing. Once discarded (used or unused) medical devices are considered to be special waste and should be managed as healthcare (clinical) waste. All medical devices that are to be disposed of, must in accordance with Health and Safety, Carriage of Dangerous Goods and Waste Regulations.
- Discarded devices should be placed in UN-type approved waste containers suitable for clinical waste (UN 3291); these should be rigid and puncture-proof. In general devices other than sharps should not be placed in sharps boxes as sharps waste is treated and disposed of in a different manner.
- Guidance on the type and color of the container should be sought from the Board Waste Management Officer. rigid water-tight containers are used for waste requiring incineration in a suitably permitted or licensed facility

Method of sterilization: Sterilized Using Ethylene Oxide

Shelf life: 5 years (from the date of manufacturing)

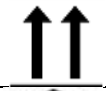
Basic UDI: 622300425TWS100678

Reporting of incident to Manufacturer & Competent Authority:

- For providing feedback on this product write to shady@ultramedumic.com
- In case of any serious incident occurred, please report it to the Ultra for medical products (Ultramed) Co (U.M.I.C) S.A.E and/or its Authorized Representative and to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

Details of symbols used in labels:

Symbol	Meaning
EU REP Obelis SA 53 Bd. Général Wahis B-1030 Brussels,Belgium Phone : 32.2.732.59.54 Fax : 32.2..732.60.03 E-mail: mail@obelis.net www.obelis.net	EU REP
CE 2803	CE Mark with notified body number 2803

Symbol	Meaning
	Sterilized by Ethylene Oxide
	For Single Use Only
	Lot No.
	Date of Manufacturing
	Use by / Expiry date
	Catalogue No.
	Non- Pyrogenic
	Medical Device
	Unique device Identifier
	Don't use if package is not intact
	Manufacturer’s address
	Phthalate-Free
	Read Instructions for Use
	Not to be re-sterilized
	storage at room temperature up to 30 ℃ ± 2℃
	Cautions
	Latex Free
	Protect from rain / Keep Dry
	Protect from sunlight / Keep away from Sunlight
	Symbol for „This way Up“
	Symbol for „handle with Care“

Symbol	Meaning
	Don’t put more than 5 cartons upon each other

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