INSTRUCTION FOR USE FOR EXTENSION TUBE

Product Name	:	**Extension Tube**
Brand Name	:	**Ultramed Extension Tubes**
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 Extension Tube is a medical device manufactured from **medical-grade PVC** with a smooth, flexible, and kink-resistant design to ensure unobstructed flow during infusion procedures. It is **phthalate-free** and **DEHP-free** for enhanced patient safety. One end is fitted with a male luer connector, while the other end is fitted with a female luer connector for secure and leak-free connections. Its robust structure maintains optimal performance even in challenging clinical conditions by minimizing the risk of occlusions or flow interruptions.
- The Extension Tube is intended for use in various healthcare settings to facilitate the administration of fluids, medications, parenteral nutrition, and other compatible solutions to patients.
- The Extension Tube is a medical device intended to connect to an IV cannula, three-way stopcock, IV administration set, infusion device, or arterial/venous catheter in order to extend the fluid pathway between the infusion, injection, or monitoring system and the vascular access site, thereby helping to reduce mechanical irritation and potential contamination risks. It is designed to facilitate the administration of fluids, medications, nutritional solutions, and other compatible medical liquids while providing secure and convenient vascular access during infusion therapy and monitoring procedures in clinical and healthcare settings.
- The Extension Tube is designed and manufactured to fulfill the applicable requirements of **ISO 8536-9**
- The Extension Tubes are provided with male or female Luer fittings incorporating a 6% Luer taper for leak proof connection with other devices as per **EN ISO 80369-7**.

Extension Tubes are available in different configurations:

- **The low-pressure extension tube** is intended for the administration of fluids and medications by gravity. It is connected to an infusion set for the administration of parenteral nutrition, fluids, and medications. The low-pressure extension tube has a priming volume of 6.46 mL per 100 cm and can withstand pressures up to 4.5 bar (65 psi).
- **The Low pressure extension tube with Three-Way Stopcock is** intended for the administration of two fluids or medications simultaneously while allowing convenient control of fluid flow.
- **The Low pressure extension tube without 3 Way Stopcock (2 Way)** is intended to provide an additional access port for administration of fluids or medications through the same IV line without disconnecting the primary infusion line.
- The Low pressure extension tube is intended for general infusion therapy applications, including the administration of fluids, medications, and nutritional solutions through venous vascular access systems under low-pressure conditions.
- **The high pressure extension tube** is designed for medical applications requiring high pressure resistance and accurate pressure transmission. It is engineered to provide durability and precision, and reliable performance in demanding clinical environments while maintaining patient safety and procedural efficiency. The high-pressure extension tube has a priming volume of 0.8 mL per 100 cm,

which helps minimize dead space and reduces the amount of fluid required for priming. The device can withstand pressures up to 55 bar (800 psi).

- The High Pressure Extension Tube is intended for use in high-pressure clinical applications, including blood pressure monitoring and the injection of contrast media during diagnostic and interventional procedures, where the device is designed to withstand elevated pressure conditions compatible with the intended use.
- Extension tubing is used to increase the length of an existing infusion line, providing improved accessibility and convenience for both healthcare professionals and patients during fluid or medication administration. However, extension tubing should be used judiciously, as additional tubing may increase dead volume and influence medication delivery characteristics. Furthermore, depending on the tubing length, internal diameter, and infusion conditions, increasing the tubing length may affect flow characteristics and potentially reduce the flow rate. Therefore, careful consideration should be given when rapid infusion rates are clinically required, such as during severe hemorrhage or hypovolemic emergencies. To minimize potential effects on infusion performance, it is recommended to connect IV infusions as close as possible to the patient access port and, when extension sets are necessary, to select and assemble components with minimal priming volume.
- Extension tube can be used for administration of parenteral nutrition, lipid, and propofol solution but Extension tube is not used for blood or blood component transfusion.
- The maximum duration of use of the extension tube for parenteral nutrition and lipid-containing solutions shall not exceed 24 hours to prevent bacterial contamination.
- The maximum duration of use of extension tube for propofol solution is not more than 12 hours to prevent bacterial contamination.
- Low pressure extension tube can withstand pressure up to 4.5 bar (65 psi).
- High pressure extension tube can withstand pressure up to 55 bar (800 psi).
- Maximum duration of use is not more than 72 hours (3 days).
- Extension tube is individually packed in a Peel pouch (medical paper and blister film)
- The product is sterilized using EO (Ethylene Oxide).
- This product is for single use.
- The quantity in multiunit container (Single box) varies according to the size and type

Low Pressure extension tube	**Quantity in Box**	**Quantity in Outer Carton**
Without Three Way Stopcock from 7 cm to 15 cm	140 Pcs	1400 Pcs
Without Three Way Stopcock from 25 cm to 50 cm	120 Pcs	1200 Pcs
Without Three Way Stopcock from 75 cm to 150 cm	70 Pcs	700 Pcs
Without Three Way Stopcock 200 cm	50 Pcs	500 Pcs
Without Three Way Stopcock 300 cm OR more	40 Pcs	400 Pcs
With Three Way Stopcock from 7 cm to 15 cm	80 Pcs	800 Pcs
With Three Way Stopcock 25 cm	70 Pcs	700 Pcs
With Three Way Stopcock from 50 cm to 150 cm	50 Pcs	500 Pcs
With Three Way Stopcock 200 cm	40 Pcs	400 Pcs
High Pressure extension tube	**Quantity in Box**	**Quantity in Outer Carton**
From 7 cm to 350 cm	80 Pcs	800 Pcs
Low Pressure Extension tube without three way (2 Way)	**Quantity in Box**	**Quantity in Outer Carton**
From 15 cm to 200 cm	50 Pcs	500 Pcs

Material Used:

- Acrylonitrile butadiene styrene (ABS)
- High-density polyethylene (H.D.P.E)
- Polyvinyl Chloride (PVC)
- Polycarbonate (PC)
- Rigid Polyvinyl Chloride (PVC)
- Polypropylene (PP)

Intended purpose:

The Extension Tube is a medical device intended to connect to an IV cannula, three-way stopcock, IV administration set, or arterial/Venous catheter to extend the pathway between the infusion and the vascular access site (venous or arterial), helping to reduce mechanical irritation and potential contamination risks. It is designed to facilitate the administration of fluids, medications, and nutritional solutions while providing secure and convenient access during infusion therapy in clinical and healthcare settings.

Variants:

Trade Name	REF (Product ID Number)
EXTENSION TUBE (High Pressure) - 7 cm	1011/HP-07
EXTENSION TUBE (High Pressure) - 10 cm	1011/HP-10
EXTENSION TUBE (High Pressure) - 15 cm	1011/HP-15
EXTENSION TUBE (High Pressure) - 25 cm	1011/HP-25
EXTENSION TUBE (High Pressure) - 30 cm	1011/HP-30
EXTENSION TUBE (High Pressure) - 40 cm	1011/HP-40
EXTENSION TUBE (High Pressure) - 50 cm	1011/HP-50
EXTENSION TUBE (High Pressure) - 60 cm	1011/HP-60
EXTENSION TUBE (High Pressure) - 70 cm	1011/HP-70
EXTENSION TUBE (High Pressure) - 75 cm	1011/HP-75
EXTENSION TUBE (High Pressure) - 80 cm	1011/HP-80
EXTENSION TUBE (High Pressure) - 85 cm	1011/HP-85
EXTENSION TUBE (High Pressure) - 90 cm	1011/HP-90
EXTENSION TUBE (High Pressure) - 100 cm	1011/HP-100
EXTENSION TUBE (High Pressure) - 120 cm	1011/HP-120
EXTENSION TUBE (High Pressure) - 125 cm	1011/HP-125
EXTENSION TUBE (High Pressure) - 140 cm	1011/HP-140
EXTENSION TUBE (High Pressure) - 150 cm	1011/HP-150
EXTENSION TUBE (High Pressure) - 170 cm	1011/HP-170
EXTENSION TUBE (High Pressure) - 175 cm	1011/HP-175
EXTENSION TUBE (High Pressure) - 180 cm	1011/HP-180
EXTENSION TUBE (High Pressure) - 200 cm	1011/HP-200
EXTENSION TUBE (High Pressure) - 250 cm	1011/HP-250
EXTENSION TUBE (High Pressure) - 260 cm	1011/HP-260
EXTENSION TUBE (High Pressure) - 300 cm	1011/HP-300

Trade Name	REF (Product ID Number)
EXTENSION TUBE (High Pressure) - 350 cm	1011/HP-350
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 7 cm	1008/LP-07
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 10 cm	1008/LP-10
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 15 cm	1008/LP-15
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 25 cm	1008/LP-25
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 30 cm	1008/LP-30
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 40 cm	1008/LP-40
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 50 cm	1008/LP-50
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 75 cm	1008/LP-75
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 80 cm	1008/LP-80
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 85 cm	1008/LP-85
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 100 cm	1008/LP-100
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 120 cm	1008/LP-120
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 125 cm	1008/LP-125
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 140 cm	1008/LP-140
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 150 cm	1008/LP-150
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 170 cm	1008/LP-170
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 175 cm	1008/LP-175
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 180 cm	1008/LP-180
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 190 cm	1008/LP-190
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 200 cm	1008/LP-200
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 7 cm	1011/LP-07
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 10 cm	1011/LP-10
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 15 cm	1011/LP-15
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 25 cm	1011/LP-25
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 30 cm	1011/LP -30
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 50 cm	1011/LP-50
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 75 cm	1011/LP-75
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 80 cm	1011/LP-80
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 85 cm	1011/LP-85
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 100 cm	1011/LP-100
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 120 cm	1011/LP-120
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 125 cm	1011/LP-125
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 140 cm	1011/LP-140
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 150 cm	1011/LP-150
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 170 cm	1011/LP-170
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 175 cm	1011/LP-175
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 180 cm	1011/LP-180
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 190 cm	1011/LP-190

Trade Name	REF (Product ID Number)
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 200 cm	1011/LP-200
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 250 cm	1011/LP-250
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 260 cm	1011/LP-260
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock - 300 cm	1011/LP-300
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock (2 Way) - 15 cm	1011/LP-15/2
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock (2 Way) - 20 cm	1011/LP-20/2
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock (2 Way) - 25 cm	1011/LP-25/2
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock (2 Way) - 50 cm	1011/LP-50/2
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock (2 Way) - 100 cm	1011/LP-100/2
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock (2 Way) - 150 cm	1011/LP-150/2
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock (2 Way) - 160 cm	1011/LP-160/2
EXTENSION TUBE Low Pressure Without 3 Way Stop Cock (2 Way) - 200 cm	1011/LP-200/2
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 10 cm (Lipid resistant)	1008/LP-10/L
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 15 cm (Lipid resistant)	1008/LP-15/L
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 25 cm (Lipid resistant)	1008/LP-25/L
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 50 cm (Lipid resistant)	1008/LP-50/L
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 100 cm (Lipid resistant)	1008/LP-100/L
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 150 cm (Lipid resistant)	1008/LP-150/L
EXTENSION TUBE Low Pressure With 3 Way Stop Cock- 200 cm (Lipid resistant)	1008/LP-200/L

Clinical Indications:

- Infusion of fluid such as Parenteral nutrition and administration of other drugs and medicines.
- Maintaining hydration and/or correct dehydration in patients who are unable to take sufficient volume of oral fluids.
- The extension tube is designed to improve accessibility and flexibility of the infusion system by increasing the distance between the patient and the infusion source, thereby supporting patient mobility, comfort, and effective infusion management, especially if the patient needs to remain in a particular position or unable to be close to the medication source.
- The extension tube is indicated for use in patients receiving intravenous therapy where reduction of tension on the vascular access site is required to help maintain catheter stability and prevent disruption of the infusion line.
- The extension tube is indicated for use in patients requiring prolonged or continuous intravenous therapy where an extended infusion line is needed to support treatment administration.
- Intravenous administration of medications, including intermittent or continuous infusion therapy.
- The extension tube is indicated for use in patients receiving intravenous therapy who require an extended infusion line to allow greater freedom of movement without dislodging the IV access.

Variant-Specific Indications

High Pressure Extension Tube

- Intended for use in high-pressure clinical applications, including blood pressure monitoring and the injection of contrast media during diagnostic and interventional procedures, where the device is designed to withstand elevated pressure conditions compatible with the intended use**.**

  Low Pressure Extension Tube
- Intended for gravity infusion of fluids and medications**.**
- Extension line suitable for low pressure applications

  Low Pressure Extension Tube with three-way stopcock
- Facilitates simultaneous administration of two compatible fluids or medications through a single vascular access site without the need for additional IV access points, reducing the risk of infection and patient discomfort.

  Low Pressure 2-way extension tube
- Allows the delivery of two compatible solutions at the same time, which meets the needs of some medical procedures and improves efficiency and safety of the intravenous injection process

Contraindications:

- Do not use in patients with known hypersensitivity or allergic reactions to any materials or components of the device

Device Limitation:

- Do not use in medical emergencies where a faster infusion is needed, as extension may reduce the flow rate
- Do not use for Administration of highly viscous fluids.
- Do not use for Blood transfusion.
- Do not use with Photosensitive and Chemotherapy drugs
- Do not use the low-pressure extension tube at pressures exceeding 4.5 bar (65 psi).
- Do not use the high-pressure extension tube at pressures exceeding 55 bar (800 psi)

Patient Target Group:

- No specific requirements or restrictions on use for patient population
- It is used for male and female patients (All ages).
- For patients requiring intravenous therapy in clinical and healthcare settings.
- The high-pressure configuration is intended for patients undergoing diagnostic or interventional procedures requiring high-pressure contrast media injection or blood pressure monitoring**.**

Intended User:

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

Application site in the body:

- The Extension Tube with or without 3-way stopcock has indirect contact with circulating blood through the connected vascular access device.
- The Extension Tube is intended for external use in connection with a vascular access device. It may be connected to peripheral or central vascular access devices

Replacement Frequency:

- Change the device immediately upon suspected contamination or if the integrity of the system is compromised (e.g., leakage, disconnection, or damage).
- Replace the IV extension set whenever the associated vascular access device (e.g., peripheral intravenous cannula) is replaced

- The maximum duration of use is not more than **72 hours (3 days)**, Replace the device after 72 hours of use or according to hospital protocol.
- The maximum duration of use of the Extension tube 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 extending the path between the vascular access site and infusion source

The clinical benefits include:

- ✓ Treatment without system length limitation
- ✓ Facilitating medication and fluid administration by providing additional distance between the patient and the infusion source
- ✓ Supporting patient mobility and reducing tension on the IV line, potentially minimizing discomfort and accidental dislodgement.
- ✓ Allowing medication administration and infusion adjustments without requiring repositioning of the patient.
- ✓ Improving infusion line organization and facilitating management of the infusion system.
- ✓ Reducing the need for frequent disconnection and manipulation at the vascular access site, potentially minimizing contamination risk.

Use Environment:

- Intended for use in healthcare settings where aseptic technique can be maintained, including operating rooms, ICUs, inpatient wards, and other clinical areas where intravenous therapy is administered.
- May also be used in outpatient settings requiring intravenous infusion 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:

- Extension Tube supplied in sterile state and sterilized using Ethylene oxide**.**

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

- The Extension Tube is intended to be used with compatible medical devices equipped with Luer connectors conforming to EN ISO 80369-7, such as IV cannulas, IV infusion sets, syringes, and other compatible devices.
- The extension tubes are provided with male and female connectors featuring a 6% Luer taper for connection to compatible medical devices in accordance with **EN ISO 80369-7**.
- **The extension tube without a 3-way stopcock** is connected to the female hub of the IV. cannula through its male Luer connector and to the male Luer connector of the IV infusion set through its female Luer connector.
- **The extension tube with a 3-way stopcock** is intended to connect with compatible IV infusion sets, syringes, and other compatible Luer connection medical devices through the female ports of the 3-way stopcock.
- **The extension tube without a 3-way stopcock (2-way)** is connected to the female hub of the IV cannula via its male Luer connector and to the male Luer connector of the IV infusion set, syringe via its female Luer connectors.

Performance Characteristics:

- **The tube** is manufactured from soft, flexible, transparent or sufficiently translucent, kink-resistant, medical-grade PVC to allow easy visualization of fluid flow and air bubbles.
- Available in various lengths ranging from 7 cm to 350 cm to meet different clinical and procedural requirements
- Phthalate-free, DEHP-free, and biocompatible materials to enhance patient safety and comfort.
- **Tubing** provides secure, leak-proof connections with both male and female connectors and withstands specified tensile forces at connector joints.
- **Male Luer connector** at one end and **Female Luer connector** at the other end facilitate secure connection to compatible medical devices, including IV infusion sets, IV cannulas, three-way stopcocks, and other Luer-compatible devices.
- Male and Female Luer connectors conform to **EN ISO 80369-7** requirements and are routinely verified using calibrated gauges to ensure dimensional compliance and compatibility.
- **Protective cap** provided on the male Luer connector to maintain cleanliness and protect the connection prior to use.
- Available **with or without three-way stopcock**, Configurations incorporating a three-way stopcock providing additional access, flexibility, and control for administration of compatible fluids and medications.
- **U-Connector** provides an additional access port for administration of compatible fluids or medications through the same IV line without disconnecting the primary infusion pathway.
- Available with or without **clamp** for temporary control of fluid flow.
- Available in **low-pressure and high-pressure** configurations to suit different clinical applications and infusion requirements.
- **Low-pressure extension tube dimensions**: approximately 2.89 mm internal diameter (I.D.) and 4.0 mm outer diameter (O.D.).
- **High-pressure extension tube dimensions**: approximately 1.8 mm internal diameter (I.D.) and 3.0 mm outer diameter (O.D.).
- Priming volume varies according to tubing length and internal diameter

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:

Before using the extension tube	
1.	Inspect Extension tube package for integrity and expiry date prior to use
2.	Perform hand hygiene and ensure aseptic conditions
3.	Apply clean gloves
4.	Open the sterile package aseptically and remove the device carefully
5.	Inspect the extension tube, connectors, and three-way stopcock (if present) to ensure all components are present and free from visible damage, including cracks, holes, scratches, obstruction, or contamination before use.
6.	Remove protective caps from the IV infusion set and extension tube connectors

During use of the extension tube

1.	Close the roller clamp of the IV infusion set completely before connection
2.	Remove the protective cap from the male Luer connector of the IV infusion set and the Luer lock plug from the extension tube
3.	**If using low pressure extension tube without three-way stopcock,** Connect the IV infusion set to the female Luer connector of the extension tube.
4.	Open the roller clamp and allow fluid to fill the extension tube completely, ensuring all air is expelled, then close the clamp after complete priming of the extension tube
5.	Remove Luer Lock Plug of IV Cannula (or intravenous catheter or other venipuncture devices) and Connect the male Luer connector of the extension tube to the female Luer of the IV cannula (or intravenous catheter or other venipuncture devices)
6.	Open the roller clamp and adjust the flow rate as prescribed.
7.	Ensure all connections remain secure during infusion Ensure the tubing is free from kinking, twisting, or obstruction, as this may affect flow
8.	**If the three way stop cock is used**, ▪ Connect the male luer of the three way stop cock to the female luer of the extension tube. ▪ Connect the female luer of three-way to the IV line. ▪ Connect the male luer of the Extension tube to the female luer of the IV cannula. ▪ Ensure all connections are secure prior to infusion
9.	**If using low pressure extension tube with three-way stopcock**, ▪ Connect the male Luer connector of the extension tube to the female Luer connector of the IV cannula ▪ Connect the IV lines to the two female Luer ports of the three-way stopcock as required for therapy
10.	**If using a high-pressure extension tube**, ensure compatibility with the intended application and securely connect all components before use

After using the extension tube	
1.	Perform hand hygiene
2.	Disconnect Extension tube with or without three-way stopcock from IV cannula using aseptic technique
3.	Dispose of the used device in accordance with institutional policy and applicable biohazard waste regulations
4.	Remove gloves and place patient in a comfortable position.

Warnings/Cautions*:*

- Carefully read all instructions prior to use and observe all warnings and cautions contained herein. Failure to follow these instructions may result in complications.
- This device is supplied sterile and ready for use. Sterility is guaranteed only if the package is unopened, undamaged, and used before the expiry date.
- For single use only. Do not reuse or re-sterilize the device.
- Reuse or re-sterilization may compromise device performance and functionality, resulting in device failure, deterioration of technical characteristics, loss of sterility, contamination, or cross infection.

- Discard the extension tube after single use in accordance with applicable local regulations and safe biomedical waste disposal procedures.
- The device should be used only by qualified healthcare professionals, including doctors or trained paramedical personnel, who have adequate knowledge of the clinical and technical aspects of the device.
- Inspect the packaging and device prior to use. Do not use the device if the package is opened, damaged, expired, or if sterility has been compromised.
- Inspect the tubing, connectors, protective caps, and all components before use. Do not use if any component is loose, missing, kinked, leaking, obstructed, cracked, or otherwise damaged.
- Use the product immediately after opening the individual blister packaging.
- Check the integrity and functionality of the extension tube before use.
- Ensure the extension tube is securely connected and properly fixed to minimize the risk of leakage, interruption of infusion therapy, or accidental disconnection.
- Use an appropriate fixation method to stabilize the extension tube during use.
- Maintain strict aseptic technique during device preparation, connection, and use to minimize the risk of contamination or infection.
- Avoid kinking or excessive bending of the tubing during use
- Monitor the patient's condition, vital signs, infusion site, and device performance during use.
- Store the device at temperatures up to 30±2 ℃. Avoid excessive heat, direct sunlight, and moisture
- Ensure the extension tube type is appropriate for the intended fluid to be administered.
- Use lipid-resistant extension tubes for administration of lipid-containing solutions. Lipophilic drugs containing lipids can be administered only with lipid resistant extension tube
- Do not use non-lipid-resistant extension tubes for lipid-containing solutions. Use of incompatible solutions or inappropriate extension tube may affect device performance or lead to material degradation, cracking, or compromised therapy delivery
- Confirm compatibility of the extension tube with the intended solution or medication prior to 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 exceed the maximum pressure of the extension tube (4.5 bar [65 psi] for low-pressure extension tubes and 55 bar [800 psi] for high-pressure extension tubes), as excessive pressure may cause tube rupture, leakage, or device failure, potentially resulting in interruption of therapy or patient harm
- Ultramed assumes no responsibility for incidental or consequential damages resulting from device reuse, reprocessing, or improper handling.
- Some organic solvents, alcoholic disinfectants might cause cracking of the device.

Potential Complications / Risks:

Potential complications with extension tubing related to device malfunctions and human use error include:

1) **Accidental Disconnection** at connection sites, leading to leakage of IV fluids, which may affect device performance and compromise patient care.
2) **Occlusion or reduced flow rate** due to tubing kinking, compression, clot/thrombus formation, or obstruction within the fluid pathway.
3) **Air embolism** resulting from improper priming or loose connections.
4) **Infection** associated with the contamination of the extension tubing, access ports, or connection sites, particularly with prolonged use or improper aseptic technique.
5) **Inaccurate medication delivery** due to increased dead-space volume.
6) **Accidental medication mixing or incompatibility** when multiple infusions are connected via stopcocks or shared infusion pathways
7) **Delayed Medication Delivery** due to tubing length.
8) **Material degradation, cracking, leakage, or compromised therapy delivery** resulting from the administration of lipid-containing solutions through a non-lipid-resistant extension tube or the use of solutions incompatible with the tubing material

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.
- Well-ventilated place
- Out of Sunlight.
- Suitable temperature **up to 30 ± 2 °C**.
- 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 obtained 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 manufacture)

Basic UDI: 622300425EXT1011XP

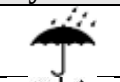
Reporting of incident to Manufacturer & Competent Authority:

- 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
STERILE EO	Sterilized by Ethylene Oxide
2	For Single Use Only
LOT	Lot No.
	Date of Manufacturing
	Use by / Expiry date
REF	Catalogue No.
	Non- Pyrogenic
MD	Medical Device
UDI	Unique device Identifier
	Don't use if package is not intact
	Manufacturer's address
PHT NON-DEHP	Phthalate-Free
	Read Instructions for Use
2 STERILIZE	Not to be re-sterilized
	storage at room temperature up to 30 ℃ ± 2℃
	Cautions
LATEX	Latex Free

Symbol	Meaning
	Protect from rain / Keep Dry
	Protect from sunlight / Keep away from Sunlight
	Symbol for „This way Up“
	Symbol for „handle with Care“
	Don’t put more than 5 cartons upon each other

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