INSTRUCTION FOR USE FOR IV INFUSION SET

Product Name : Intravenous Infusion Set

Brand Name : Ultramed I.V Infusion Set

Manufacturer's Name : Ultra for medical products (Ultramed) Co (U.M.I.C) S.A.E

Manufacturer's Address : Part no. (304 : 310) and part no. 312 - Arab El Awamer - Industrial zone – Abnoub – Assiut, Egypt.

- ***Description of the Device:***

- IV Infusion Set consists of a cylindrical collapsible drip chamber to visualize the Drip Rate. with Sharp piercing spike for easy insertion in I.V container, Air-vented IV Infusion set with built in air vent and bacteria barrier hydrophobic filter. Disc type 15 µm fluid filter at the bottom of drip chamber filters any particulate matter in the I.V fluid. Provided with super smooth kink resistant flexible tube (phthalate free and DEHP free) for unobstructed flow., it is for administration by gravity, Efficient roller clamp controller ensures better flow control., Provided with "Y" type injection port for additional medication. latex bulb for intermittent medication. Luer lock (6% luer taper) for secure connection to all standard devices. Sterile, disposable, non-pyrogenic, individually packed. It is provided with / without needles. IV infusion set can be available with latex bulb, male fitting and needle or available with male luer and cover male luer. 20 Drops of distilled water equivalent to 1 ml ± 0.1 ml. IV infusion Set with microneedle is provided with microneedle. 60 Drops of distilled water equivalent to 1 ml ± 0.1 ml. IV Infusion Set with flow regulator is provided with flow regulator for accurate adjustment of flow control of I.V. fluids with range of 5 to 250 ml/hr.
- Infusion set is individually packed in a Peel / Tear pouch.
- Polybag of 25 single units.
- Maximum use period is not more than 3 days.
- The product is sterilized using EO (Ethylene Oxide)
- This product is for single use.

Material Used:

- (L.D.P.E) Low Density polyethylene
- ABS (Acryl nitrile butadiene styrene)
- Class fiber
- DEHP free P.V.C (Poly Vinyl Chloride) medical grade
- Polypropylene (P.P) medical grade+ Master Batch (Blue& White)
- Synthetic rubber for Y site injection port.
- Natural rubber(latex) for latex bulb.
- (H.D.P.E) High-density polyethylene medical grade
- S. Steel Needle

Intended purpose:

- The Infusion Sets are used to administer Intravenous fluid such as parenteral nutrition and administration of other drugs and medicines into human circulating system. Maintaining hydration and/or correct dehydration in patients who are unable to take sufficient volume of oral fluids

Variants:

Ref Code	Item
1009	Intravenous Fluid Infusion Set With Non-Vented Spike
1012	Intravenous Fluid Infusion Set – Micro Drip Set
1013	Intravenous Fluid Infusion Set With Flow Regulator
1014	Intravenous Fluid Infusion Set With Air-Vented Spike

Clinical Indications:

- The Infusion Sets are used to administer Intravenous fluid and medicines into human circulating system.
- If a patient is ill and has fluid loss related to decreased intake, surgery, vomiting, diarrhea, or diaphoresis, the patient may require IV therapy.
- To replace fluids and electrolytes and maintain fluid and electrolyte balance: The body's fluid balance is regulated through hormones and is affected by fluid volumes, distribution of fluids in the body, and the concentration of solutes in the fluid.
- To administer medications, including anesthetics, About 40% of all antibiotics are given intravenously.
- To deliver nutrients and nutritional supplements: IV therapy can deliver some or all of the nutritional requirements for patients unable to obtain adequate amounts orally or by other routes.

Contraindications:

- Some patients have anatomy that poses a risk for fluid extravasation or inadequate flow and peripheral IVs should be avoided in these situations.
- Examples include extremities that have massive edema, burns or injury.
- For the patient with severe abdominal trauma it is preferable to start the IV in an upper extremity because of the potential for injury to vessels between the lower extremities and the heart.
- For the patient with cellulitis of an extremity, the area of infection should be avoided when starting an IV because of the risk of inoculating the circulation with bacteria. As well, extremities on the side of a mastectomy or that have an indwelling fistula should be avoided because of concerns about adequate flow.
- Do not use in patients with known hypersensitivity to any of the product components.

Device Limitations:

- Do not use for administration of highly viscous fluids.
- Do not use for Blood transfusion

Patient Target Group:

- No specific requirements or restrictions on use for patient population or user group defined by the manufacturer.
- Adult & Pediatrics.
- It is used for male and female patients (all Ages).
- Intravenous therapy is an effective and fast-acting way to administer fluid or medication treatment in an emergency situation
- For patients who are unable to take medications orally. Approximately 80% of all patients in the hospital setting will receive intravenous therapy.

Application site in the body:

- The medical device Infusion set is in-direct contact with patients' blood
- Intravenous route.

Replacement Frequency:

- Change the device immediately upon suspected contamination.

Intended User:

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

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 fluids such as solutions, parenteral nutrition, medicines and to maintain hydration in patients who are unable to take sufficient volume of oral fluids.

Use Environment:

- Hospital, Emergency Room, Critical care room

Life time of device:

- Maximum use period is not more than 3 days for normal fluids and nutrition.
- Maximum duration of use of IV infusion set for lipid containing fluids is not more than 24 hours to minimize the risk of bacterial contamination.

Sterility status and Method of sterilization:

- Infusion set is supplied in sterile state and sterilized using ethylene oxide.

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

- Infusion set is designed to be connected with IV Cannula, Infusion bottle, Three-way stop cock, etc. Spike of an Infusion Set is designed as per ISO 8536-4 for safe connection with Infusion container. For connection with other devices distal end of the Infusion Set is provided with a 6% taper male luer as per ISO 80369-7.

Performance Characteristics:

- Clear, transparent & flexible drip chamber.
- Soft and kink-resistant tube.
- Accurate flow controller.
- Tube(Phthalate free and DEHP free)
- 20 drops equal to 1±0.1ml of distilled water
- 60 drops equal to 1±0.1ml of distilled water for IV infusion Set with micro drip.
- Tube length: 150cm, 180cm & 200cm

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:

- Check the packing carefully, if packing is found damaged, torn or pierced, discard the piece.
- Wash-up and scrub hands and preferably use sterile protective gloves.
- Peel / Tear open the pouch and take out the device aseptically.
- Make a visual inspection on the device before use.
- Close flow regulator or Close completely flow control clamp.
- If a rigid or semi-rigid container is used, the container shall be cut open at the top to provide a freely vented system or open the air-vent cap in case of using the air-vented spike. Insert the closure-piercing device of the infusion set into the container or bag port. Fill the drip chamber to be about ⅔ full. Open the flow regulator or roller body and fill the complete infusion set.
- Remove the needle protector. Open the flow control clamp gradually allowing the solution to displace air entirely in tube and needle. Then close clamp tightly. Perform vein puncture & regulate the flow rate by opening the clamp gradually.
- In case the device is without needle Remove protective cap from the adaptor at connector end and connect with venous access device.
- If medication is being given for the first time, stay with the patient for the first 5 minutes to monitor for any potential adverse effects.
- Encourage patient to notify the health care provider if IV site becomes red, painful, or swollen, or if patient notices any adverse effects from the medication.

- Warnings:

- For Single use.
- Discard after single use, Reusing can be associated with Cross infection, Device Malfunction and Reactions to endotoxins as sterilization will not inactivate toxins produced by the breakdown of Gram-negative bacteria even if the bacteria themselves are killed.
- DO NOT re-sterilize and /or reuse the device, as this can compromise the device performance (functionality) 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.
- The product should be used only by qualified doctors or paramedics who are experienced and have a thorough understanding of the clinical and technical aspects of product.
- Do not attempt to re-insert a partially or completely withdrawn needle.
- Re-use of single use device creates a potential risk for patient or user. It may lead to contamination and / or impairment of functional capability.
- Contamination and / or limited functionality of the device may lead to injury, illness of the patient.
- Use Y site (If applicable) only for injecting the medicine intermittently using aseptic technique.
- Close the air-vent during periods of interrupted infusion therapy.
- Some organic solvents, alcoholic disinfectants, infusion solutions with high pH-value substances might cause cracking of the device.

- Reuse and cleaning of product may alter their structural and mechanical properties. It may lead to infection or other illness/injury.
- Store in between 5º to 32º C, avoid excessive heat, protect from direct sunlight and moisture.
- The device should be disposed as per the safe disposal instructions as described in the instructions for use.
- The product should be replaced and disposed as per facility approved protocol or CDC guidelines.
- ULTRAMED will not be responsible for any direct incidental or consequential damages resulting from reuse of product.

- ***Precautions:***

- Carefully read all instructions prior to use.
- Observe all warnings & precautions noted throughout these instructions.
- Failure to do so may result in complications. This device is Sterile & Ready for Use. Sterility is guaranteed - if pack is undamaged.
- The device is for Single Use Only.
- Do not use if package is open or damaged.
- Use Y site injection port only for injecting the medicines.
- Check the integrity and functionality of the Infusion sets before use.
- Do not use if protective cap is loose or missing.
- IV infusion set is used for administration of fluid and medications by gravity
- Use the product immediately after opening the individual blister packing.
- Close the air-vent during periods of interrupted infusion therapy.
- Do not re-sterilize.
- Discard the set after single use.
- This device does not contain phthalates (DEHP FREE); as marked.
- Determine patient's condition and vitals status During device application / Operation.
- Conduct procedure under strict surgical protocol and ensure complete asepsis.
- Destroy the device & its accessories after single use as bio-medical waste as per applicable laws.
- Do not Re-sterilize.
- Do not Re-use.
- Single use only
- Check the Date of Expiry before use.

Potential Complications / Risks: Risk from improper fitment due to faulty 6% luer taper, Leakage & blockage, any broken / cracked part / less clear drip chamber and tube /components, kinking, un-proper tip of piercing spike, faulty air passage in vented piercing spike, uncontrolled flow, malfunction due to leakage or blockage:
Embolism, Allergic reactions, tissue necrosis, Infiltration, Hematoma, Extra Vascular drug administration, Phlebitis, Septicemia, Pulmonary Edema/ Embolism, Air embolism.

General Instructions:

To be used by an expert qualified medical professional. Use maximal sterile barrier precautions during administration Dispose the device after use as bio-medical waste as per applicable laws.

Conditions of Handling, Preservation and Storage:

- Not more than 5 cartons on each other.
- Nice Ventilated place.
- Out of Sunlight.
- Suitable temperature from 5º C to 32º 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 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)

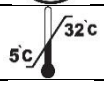
Basic UDI: 622300425IVS1009Z3

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
EC 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

Symbol	Meaning
	CE Mark with notified body number 2803
	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 temperature from 5 ℃ to 32 ℃
	20 drops/ml
	60 drops/ml
	Cautions
	This product contains latex
	Latex Free
	Protect from rain / Keep Dry

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

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