INSTRUCTION FOR USE FOR IV INFUSION SET

Product Name : Blood Administration Set

Brand Name : Ultramed Blood Administration 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:*

- Blood Administration Set is a medical device used to safely deliver blood or its components from the blood bag to the patient intravenously using gravity.
- Blood Administration Set consists of a collapsible drip chamber to visualize the Drip rate, delivering **20 drops = 1 ± 0.1 mL of distilled water**, with Sharp piercing spike for easy and safe penetration of the blood bag. A 200µm filter Located inside the drip chamber that filters any particulate matter in the blood, ensuring clean and safe blood flow. It is provided with a super-smooth, kink-resistant flexible tube (phthalate free and DEHP free) for unobstructed flow, An Efficient roller clamp allows control the flow of the blood and blood component from zero to the maximum with the color coded red roller to easily identify the purpose of this set. A Bulb is included for manual control of blood flow by squeezing or releasing it. A Male Luer (6% luer taper) or Male fitting designed according to ISO 80369 ensures secure connection to all standard devices. The set is designed for blood administration by gravity.
- The Blood Administration Set may be provided with a "Y" site injection port.
- The Blood Administration Set may be provided with / without needles.
- The Blood Administration Set is sterile, disposable, non-pyrogenic, individually packed in a peel pouch
- Each polybag contains 25 units, and each carton includes 16 polybags, totaling 400 units per carton
- Maximum duration of use is not more than 4 hours according to AABB.
- 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
- (P.P) Polypropylene medical grade
- S. Steel Needle

Intended purpose:

- Blood Administration Set is intended to deliver blood or blood components such as red blood cells, platelets, and plasma from the container into the patient's bloodstream through a needle or a catheter inserted into a vein by gravity-fed administration.

Variants:

Ref Code	Item
7007	Blood Administration Set

Clinical Indications:

- According to the American Red Cross & NIH (NCBI) guidelines, Common types of blood transfusions include red blood cell, platelet and plasma transfusions.

- **Red Blood Cell Transfusion**
  - A patient suffering from an iron deficiency or anemia, a condition where the body does not have enough red blood cells, may receive a red blood cell transfusion. This type of transfusion increases a patient's hemoglobin and iron levels, while improving the amount of oxygen in the body.
  - Critically ill patients or gastrointestinal (GI) bleeding with hemoglobin ≤7 g/dL
  - Patients with coronary artery disease or undergoing orthopedic surgery when Hb ≤8 g/dL
  - Active or acute bleeding caused by trauma, surgery, or internal hemorrhage and patients with symptoms related to anemia (for example, tachycardia, weakness, dyspnea on exertion) and hemoglobin less than 8 g/dl
  - Patients with anemia who have evidence of impaired oxygen delivery. For example, individuals with acute blood loss, chronic anemia and cardiopulmonary compromise, or disease or medication effects associated with bone marrow suppression may be candidates for RBC transfusion.
- **Fresh Frozen Plasma (FFP) Transfusion**
  - Plasma transfusions are used for patients with liver failure, severe infections, and serious burns.
  - Patients with bleeding due to coagulation factor deficiencies
  - Patients undergoing cardiopulmonary bypass, massive transfusion, extracorporeal pulmonary support, acute disseminated intravascular coagulation, or decompensated liver disease.
- **Platelet Transfusion**
  - Often transfused for patients suffering from leukemia, or other types of cancer, have lower platelet counts as a side effect of their chemotherapy treatments. Patients who

have illnesses that prevent the body from making enough platelets have to get regular transfusions to stay healthy.

- Patients with platelet deficiency or dysfunction.
- Patients with bone marrow failure, **prophylactic platelet** transfusion is indicated when there are no other risk factors for bleeding and platelet counts are below 10 X 10/L. If other associated risk factors exist, the threshold to transfuse may be raised to 20 X 10/L
- Patients undergoing invasive procedures who require platelet counts >50 × 10/L
- Actively bleeding patients with platelet dysfunction or counts <50 × 10/L
- Patients with diffuse microvascular bleeding requiring levels >100 × 10/L

- **Cryoprecipitate Transfusion**
  - Patients with fibrinogen deficiency or dysfibrinogenemia in the presence of bleeding
  - Patients with acute DIC or undergoing invasive procedures where fibrinogen replacement is required
- **Transfusion may be indicated in certain cases of** acute sickle cell complications (such as stroke or acute chest syndrome), in cancer patients with symptomatic anaemia or bleeding, in kidney disease patients when anaemia is severe and symptomatic, in hemophilia, in severe traumatic hemorrhage, hemorrhagic shock, and massive bleeding.

Contraindications:

- Do not Use in patient with a known allergic reaction to any of the product components.
- Do not use the blood set if there is any mismatch between the patient's blood type and the blood component intended for transfusion, as this may cause a severe hemolytic transfusion reaction.
- Do not use dextrose in a giving set before or after blood, as it can cause haemolysis.
- Do not add drugs to any blood component pack or use the same infusion line for administering medications according to NHS guidelines.
- Do not mix dextrose solutions (such as 5% dextrose) with blood components due to the risk of haemolysis according to NHS guidelines.
- Do not use calcium-containing solutions, as they may cause clotting of citrated blood according to NHS guidelines.
- Do not use RBC transfusions to increase intravascular blood volume, as they are intended primarily to improve oxygen-carrying capacity rather than fluid support.

Device Limitations:

- Do not use this set for the infusion of any fluids other than blood or blood components.
- Do not use the blood administration set with an infusion pump, as it is specifically designed for gravity-fed transfusion only.
- Do not use gravity-fed blood administration set for massive 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).

Application site in the body:

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

Replacement Frequency:

- Change the device immediately upon suspected contamination.
- Do not use the device more than 4 hours.

Intended User:

- To be administered by an expert qualified medical professional, Skilled Or Trained Personnel (In-Charge).
- Personnel who participate in the administration of blood components must be trained in transfusion procedures and in recognition and management of adverse reactions.
- All health care practitioners who administer blood or blood Components must complete specific training for safe transfusion practices and be competent in the transfusion administration process.

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 blood or blood components such as red blood cells, platelets, and plasma from the container into the patient's bloodstream by gravity.

Use Environment:

- Hospital, Emergency Room, Critical care room

Life time of device:

- Maximum use period not more than 4 hours.

Sterility status and Method of sterilization:

- Blood Administration Set supplied in sterile state and sterilized using ethylene oxide.

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

- Blood Administration set is designed to be connected with IV Cannula, Blood bag, etc. Spike of the blood administration is designed as per ISO 1135-4 for safe connection with blood bag. For connection with other devices distal end of the blood administration set is provided with a 6% taper male luer as per ISO 80369-7.

Performance Characteristics:

- Strong and sharp spike to puncture blood bag outlets.
- Clear, transparent & flexible drip chamber.
- Contain a 200 µm filter to remove clots and aggregates.
- Soft and kink-resistant PVC tube (Phthalate free and DEHP free).
- Roller clamp adjusting blood flow
- 20 drops of distilled water equivalent to 1±0.1ml [(1 ± 0,1) g]
- 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:

Preparing for a Blood or Blood Components Transfusion.

- Be diligent when preparing to infuse blood. Distractions may lead to errors when verifying information.
- Get informed consent from the patient for the transfusion.
- Before Carrying out a blood transfusion, Inform the Patient about the reasons for transfusion and discuss the risks, symptoms of transfusion reaction.
- Verify the physician's order for the specific blood or blood components, Order must be verified for the type of product; the amount, date, time, and rate and duration of infusion.
- Verify the health care provider's orders for any pre- or post-transfusion medications to be administered.
- Obtain the patient's transfusion history, and note any known allergies and previous transfusion reactions as Past complications may require patient to have pre- and post-transfusion medications to prevent further transfusion reactions.
- Verify that blood type matches on Transfusion record and blood bag. Verify that component received from blood bank is the same component physician or health care provider ordered.
- Check that patient's blood type and Rh type are compatible with the blood component intended for transfusion.
- If the name and identification number recorded on the Unit Tag attached to the unit do not correspond with that of the intended recipient, the component must be returned to the Transfusion Service. Consult with the Transfusion Service if there is any question.
- If a blood component cannot be transfused shortly after being received from the Transfusion Service, immediately return it to the Transfusion. To avoid waste, notify the Transfusion Service that blood is being returned.
- Establish IV site or verify patency of current site. IV sites must be patent and without complications such as infiltration or phlebitis. The IV cannula must be large enough to allow flow of product at the correct rate. Blood and blood components cannot be mixed with IV medications. If necessary, establish a site specifically for the blood component. This will allow the blood transfusion to be initiated as soon as the component arrives on the patient unit.
- Be prepared for potential complications, as prompt intervention may be required to prevent serious outcomes. Ensure emergency equipment (oxygen, suction, etc.) is available at the bedside.
- Obtain and record the pre-transfusion baseline vitals including temperature, pulse, respirations, blood pressure, and SpO_2.

- Medications must not be added to blood units or infused through the same IV tubing used for blood administration.
- All blood components taken from the blood bank must be hung within 30 minutes and administered (infused) within 4 hours due to the risk of bacterial proliferation in the blood component at room temperature.

Transfusion of Blood and Blood components.

1- Wash-up and scrub hands and preferably use sterile protective gloves.
2- Check the packing carefully, if packing is found damaged, torn or pierced, discard the piece
3- Peel open the pouch and take out the device aseptically.
4- Blood set should be carefully checked to ensure that there is no damage. Damaged blood set must not be used.
5- Close completely flow control clamp [Roller Body]
6- Check the blood bag for leaks, clots, or discoloration. Ensure the blood bag is within the expiration date.
7- Prepare blood component for administration. Gently agitate blood unit bag. Remove protective Covering from access port.
8- Remove the spike protector and insert the full length of the spike into the blood/blood component bag or the saline container to begin priming. The set may be primed with the component being transfused or 0.9% Sodium Chloride ('normal saline')
9- Only isotonic saline (0.9%) is recommended for use with blood components. Other commonly used intravenous solutions will cause varying degrees of difficulty when mixed with red cells. For example, 5% dextrose in water will hemolyze red cells. Intravenous solutions containing calcium, such as Lactated Ringer's solution, can cause clots to form in blood.
10- Suspend container & fill the drip chamber half full by squeezing and releasing
11- Remove the needle protector. Open the flow control clamp gradually to prime the line, ensuring all air is displaced from the tube and needle. Then close clamp tightly.
12- Perform vein puncture or connect the male luer of blood set to the IV cannula.
13- Gradually Open the flow control clamp [roller body].
14- Start the infusion slowly to allow for recognition of an acute adverse reaction.
15- Remain with patient during the first 15 minutes of a transfusion and monitor the patient closely for any signs of adverse reactions (e.g., fever, rash, chills, shortness of breath). If a reaction occurs, stop the infusion immediately and notify the healthcare provider. The patient must be assessed and stabilized, the blood bank must be notified, and a transfusion reaction investigation should be initiated.
16- Monitor the patient's vital signs 15 minutes after initiation, and then hourly until the transfusion is complete or as per agency policy.
17- If there is no transfusion reaction, regulate rate of Transfusion according to physician's orders
18- Safety Alert Do not let a unit of blood hang for more than 4 hours, because bacterial growth can occur. Never store blood in a facility refrigerator. SAFETY ALERT Never inject

medication into the same IV line with a blood component because of the risk for contaminating the blood product with pathogens and the possibility of incompatibility. A separate IV access must be maintained if the patient requires medications.

19- Advise patient on the signs and symptoms of transfusion reaction and when to report.

20- Encourage patient to notify the health care provider if transfusion site becomes red, painful, or swollen, or if patient notices any adverse effects from the transfusion

21- After blood has infused, appropriately dispose of all supplies. Remove gloves, and perform hand hygiene.

22- Monitor IV site and status of infusion each time vital signs are taken.

23- Observe for any changes in vital signs and for chills, flushing, itching, dyspnea, rash, or other signs of transfusion reaction.

24- Assess and observe for clinical signs and symptoms of reactions up to 48 hours' post-transfusion.

- ***Warnings:***
- For Single use.
- Discard after single use, Reusing can be associated with Cross infection, transmission of bacteria, viruses and blood Related transfusion of serious diseases, 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.
- Re-use of single use device creates a potential risk. 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.
- Do not attempt to re-insert a partially or completely withdrawn needle.
- Storage up to 30^{o} C ± 2°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.
- Do not use if protective cap is loose or missing.
- Do not use the blood administration set with an infusion pump.
- This device does not contain phthalates (DEHP FREE); as marked.
- Determine patient's condition and vital status During device application / Operation.
- Conduct procedure under strict surgical protocol and ensure complete asepsis.

- Do not administer blood components to patients with a previous history of severe allergic reactions or anaphylaxis to blood components without thorough clinical evaluation and appropriate precautions, due to the high risk of recurrent life-threatening reactions.
- Do not use a blood administration set for longer than 4 hours after starting the transfusion, due to the increased risk of bacterial contamination and patient harm.
- Do not use whole blood when specific blood components are indicated and available, since this may increase the risk of complications such as volume overload
- Do not use small size catheters for whole blood or packed cells — high resistance can cause hemolysis.
- In certain clinical situations, alternative therapeutic methods may be more appropriate and effective than blood transfusion. The decision to administer a transfusion should always be based on the patient's clinical condition and the physician's judgment. For example, in cases such as megaloblastic anemia, treatment with specific medications (e.g., vitamin supplementation) may be preferred. Consideration must always be given to the general risks associated with blood transfusion.
- In patients with active septicemia or severe infections, blood transfusion should be performed only after careful clinical assessment. Although the transfusion set itself is not contraindicated, transfusion may increase the risk of inflammatory or circulatory complications.
- Ultramed will not assume any responsibility in case of any incidental or consequential damages resulting from reuse of the 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.
  - Check expiry date prior to use.
  - Do not use if package is open or damaged.
  - Use the device immediately after opening the individual pack.
  - Check the integrity and functionality of the Blood transfusion set before use.
  - Always follow institutional or agency protocols for managing transfusion reactions. Monitor patients closely for mild reactions (e.g., transient fever). The decision to continue or discontinue the transfusion should be based on the clinical status of the patient and the judgment of the responsible physician. For all other or severe reactions, stop the transfusion immediately and initiate appropriate medical management.
  - Be aware that blood transfusion reaction may occur 24 to 48 hours' post-transfusion.
  - It is important that a healthcare professional uses the correct blood type during a blood transfusion. Otherwise, the body might reject the new blood, which can have severe consequences.
  - Follow emergency transfusion guidelines when dealing with an emergency blood or blood components transfusion.

- Be aware of which types of blood or blood components cause the most types of transfusion reactions
- Be aware of the types of patients at high risk for blood or blood components transfusion reactions.
- Always have emergency equipment and medications available during a transfusion. For example, epinephrine IV should always be readily available.
- In patients with heart failure, renal failure, or other conditions that predispose them to fluid overload, blood transfusions should be done carefully, and the use of the administration set should be monitored closely.
- All blood components taken from the blood bank must be hung within 30 minutes and administered (infused) within 4 hours due to the risk of bacterial proliferation in the blood component at room temperature.
- If a transfusion reaction is suspected, the transfusion should be stopped, the patient must be assessed and stabilized, the blood bank must be notified, and a transfusion reaction investigation should be initiated.
- A nurse or doctor should check the patient's blood pressure, pulse, and temperature 30 minutes before starting the transfusion. As The pretransfusion vital signs provide a baseline for comparison data obtained during and after transfusion.
- Check vital signs every 15 minutes until stable as vital signs must be monitored to identify improving or worsening condition.
- Following the completion of the blood transfusion, the patient's vital signs are checked.
- If there are indications that the product has been damaged or contaminated or the protective cap has been removed and allows the entry of some dust and other particles, refrain from using the product.
- Medications given prior to transfusion are only considered for persons with documented moderate to severe reactions. Typically, medications are administered 30 minutes prior to the transfusion.
- Once the product has been opened, use it immediately. Do not procrastinate using it because if you do so, you allow its contamination.
- Destroy the device after single use as bio-medical waste as per applicable laws.
- Do not use the device after the Expiry Date.

Potential Complications / Risks: Risk from improper fitment due to faulty 6% luer taper, Leakage & blockage, any broken / cracked part / less clear drip chamber and tubing /components, kinking, un-proper tip of piercing spike, malfunction due to leakage or blockage, extravasation, pulmonary edema, air embolism, Allergic reactions, Infiltration, Hematoma, Phlebitis, Septicemia, transfusion-associated circulatory overload (TACO), Bacterial Contamination, microclots, cellular aggregates, Hemolysis, faulty roller clamp.

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.

Important Information:

Certain cultural or religious beliefs such as those held by Jehovah's Witnesses may prohibit or restrict the acceptance of blood transfusion. In accordance with national laws and hospital policies, informed consent should be obtained from the patient prior to starting a transfusion. In cases where the patient is unconscious or unable to provide consent, authorization should be obtained from the patient's family or legal representative. The patient, their family, or legal representative should be informed about the risks, symptoms and benefits of blood transfusion prior to the procedure. following the applicable legal and ethical requirements in the respective country.

Conditions of Handling, Preservation and Storage:

- Not more than 5 cartons on each other.
- Nice Ventilated place.
- Out of Sunlight.
- Storage at room temperature up to 30℃ ± 2℃.
- Humidity: 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: 622300425BTS7007VQ

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
CE 2803	CE Mark with notified body number 2803
STERILE EO	Sterilized by Ethylene Oxide
	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

Symbol	Meaning
	Read Instructions for Use
	Not to be re-sterilized
	storage at room temperature up to 30 ℃ ± 2℃
	20 drops = 1 ± 0.1 mL of distilled water
	Cautions
	Gravity Feed Only
	Filter of liquid with pore size
	This product contains latex
	Latex Free
	Protect from rain / Keep Dry
	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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Alexandria Office: 212Abd El salaam Airef Str, Luran **Tel:** 03/5856202– 5856458 & **Fax:** 03/5828988& **Mob:** 0123948666
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