# IFU of Measured Volume Fluid Administration Set (Burette Set)

**Manufactured by Mais India Medical Devices Pvt. Ltd.**

**Intended Use:**
A burette set is a specialized medical device used for the precise and controlled administration of intravenous (IV) fluids, particularly when a specific, limited volume needs to be infused. Its primary purpose is to deliver accurate doses of medications or fluids, especially in situations where fluid overload is a concern.

**Materials Used:**
Linear Low Density Polyethylene (LLDPE), Polyvinyl Chloride (PVC), Acrylonitrile Butadiene Styrene (ABS), Isoprene, Stainless Steel, Nylon, Acrylic Copolymer Membrane.

**Indications:**
· To accurately measure and control the volume of IV fluids or medications, especially for patients who require restricted fluid intake.
· To ensure very small, precise volumes of fluids and medications are delivered to infants and children, preventing fluid overload.
·To administer specific, controlled doses of intravenous drugs over a set period.

**Contra Indications:-**
· This product should not be used on patients with a known hypersensitivity or allergy to any of the materials it's made from.
· The burette set is not suitable for the administration of high-viscosity fluids.
· Cannot be used for blood transfusions.

**Instructions for use:**
· Sanitize your hands with an alcohol-based cleanser and put on gloves.
· Open the burette set packaging and inspect it for any damage.
· Close all clamps on the burette set.
· Spike the IV fluid bag with the spike from the burette set. Ensure a secure connection.
· Hang the IV bag on an IV pole.
· Fill the burette chamber by opening the clamp below the IV bag.
· Fill the chamber to the desired volume, typically a specific amount of fluid or medication. Use the markings on the side of the burette for accurate measurement.
· Close the clamp to stop the flow from the IV bag.
· If Y-site is applicable, use a sterile syringe to inject through the Y-site (ensure compatibility and prescription).
· Open the roller clamp on the drip tubing below the burette chamber.
· Allow the fluid to flow through the tubing, ensuring all air bubbles are removed.
· Close the roller clamp once the tubing is fully primed
· Connect the end of the burette set to the patient's IV catheter.
· Open the roller clamp to begin the infusion at the rate prescribed by a healthcare professional.
· Monitor the drip chamber to confirm the fluid is flowing correctly.
· Periodically check the burette chamber to ensure the correct volume is being infused and monitor the patient for any adverse reactions.
· Once the infusion is complete or if the patient's condition changes, follow your facility's protocol to discontinue the IV.
· Disconnect the burette set and dispose of it, along with the IV tubing, in the appropriate medical waste container.

**Medical conditions:**
· To read "instruction for use" carefully before use of the product.
· The use of the product is restricted to a qualified doctor or a paramedic staff.

**Warnings:**
· The use of this product is restricted to a qualified doctor or a paramedic.
· Read instructions before use.
· MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.
· The product should not be reprocessed.
· Visually inspect and carefully check the product and packaging before use.
· Improper transport and handling may cause structural and/or functional damage to device or its packaging.
· The product is non-toxic, sterile & non-pyrogenic.
· Do not clean or re sterilize. For single use only. Discard after use.
· Re-use of single-use devices creates a potential risk(i.e bloodstream infection) of patient or user.
· If the device is reused, then it may cause a bacterial infection in patient, and also may lead to contamination and/or impairment of functional capability, which may in turn lead to patient injury.
· If you notice any change in the device's performance or if it malfunctions, immediately remove it. The device should then be sent back to the supplier for a full investigation.
· Store in a cool & dry place.
· Do not expose to heat or direct sunlight.
· The product should be used immediately after its packaging is opened.

**Cautions:**
· Never attempt to reuse a device that has already been used on a patient. Dispose of the used device and replace it with a new one.
· If you notice that the fluid is not flowing properly after setting up the burette set, there may be a problem with the device or the IV line. In this case, you should:
  · **Remove and Discard:** Immediately stop the infusion, remove the existing burette set, and dispose of it according to your hospital's policy.
  · **Replace:** Use a new, sterile burette set to try again
· Do not use if the packaging is damaged.
· When removing the device, be careful not to use any sharp objects or tools that could damage the IV line or injure the patient.

**Target Age Group:**
For All age groups

**Duration of Contact of Device:**
Up to 72 Hours for best performance.

**Storage conditions:**
Store at a temperature at +10°C and +40°C, humidity between 40% to 60%, in a dry place and away from sunlight.

**Device Life:**
05 Years

**Explanation of symbols used:**

| Symbols | Title of the Symbol | Symbols | Title of the Symbol |
|---|---|---|---|
|  | Consult instructions for use (Indicates the need for the user to consult the instructions for use) |  | Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified) |
|  | Caution (To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.) |  | Date of manufacture (Indicates the date when the medical device was manufactured) |
|  | Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide) |  | Use-by date (Indicates the date after which the medical device is not to be used) |
|  | Indicates product that does contain the phthalate plasticizers DEHP. |  | Contains or presence of phthalate plasticizers DEHP |
|  | Latex free (Indicates a medical device that is Latex free) |  | Latex (Indicates a medical device that is Latex) |
|  | Do not re-sterilize (Indicates a medical device that is not to be re-sterilized) |  | Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified) |
|  | Do not re-use (Indicates a medical device that is intended for one single use only) |  | CE Mark |
|  | Non-pyrogenic (Indicates a medical device that is non- pyrogenic) |  | Keep away from sunlight (Indicates a medical device that needs protection from light sources) |
|  | Do not use if packaging is damaged and consult instructions for use. (Indicates a medical device that should not be used if its packaging has been damaged or opened, and that the user should consult the instructions for use for additional information) |  | Authorized representative in the European Community / European Union (Indicates the authorized representative in the European Community / European Union)<br>OBELIS S.A.<br>Boulevard Général Wahis 53, 1030 Brussels, Belgium<br>Contact Number: +32(2)73 25 954<br>Email ID: regulatory@obelis.net<br>Website: www.obelis.net |

| Symbols | Title of the Symbol | Symbols | Title of the Symbol |
|---|---|---|---|
|  | Keep dry (Indicates a medical device that needs to be protected from moisture) |  | Manufacturer (Indicates the medical device manufacturer)<br>Manufacturing Unit:<br>525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India.<br>Contact Details.: +91 8527589990<br>Fax No.: 0124 404 7533<br>Email ID: info@maisindia.com<br>Website:www.maisindia.com |
|  | Single sterile barrier system (Indicates a single sterile barrier system) |  | Country of manufacture (To identify the country of manufacture of products) |
|  | Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information) |  | Medical device (Indicates the item is a medical device) |
|  | Humidity limitation (Indicates the range of humidity to which the medical device can be safely exposed. |  | Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed. |
|  | This way up |  | Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully) |

**Manufactured for:**
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