Front Side:-

IFU of Burette Set/Measured Volume Set (M.V. Set)

Manufactured by Mais India Medical Devices Pvt. Ltd.

General Device Description:
The Burette Set (M.V. Set) is a sterile, single-use device designed for precise IV administration of fluids and medications, featuring a measuring chamber for accurate volume control during infusion therapy.

Product Name:
Burette Set / Measured Volume Set (M.V. Set)

Variants:
1. Standard
2. Premium
3. Standard with Y-Site
4. Standard with Needle free Y-Site

Sizes:
110 ml & 150 ml.

Intended Use:
The device is intended for continuous and accurate flow rate adjustment, preventing air embolism through its safety shut-off valve, and enables the addition of supplementary medication as clinically required.

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

Indications for use:
1. Precise fluid delivery
2. Controlled medication administration
3. IV fluid therapy

Contra Indications:
It is not intended for the administration of whole blood, blood components.

Intended Patient Population:
Adult, pediatric, and neonatal patients requiring controlled intravenous fluid administration.

Intended User:
Healthcare Professionals

Use environment:
Proper Healthcare Setup

Instruction for use:
1. Check the sterile package for integrity. Do not use if the package is damaged or the expiry date has passed.
2. Hang the IV fluid container on the IV stand.
3. Close the roller clamp of the Burette Set (M.V. Set).
4. Remove the protective cover from the spike and insert the spike into the IV fluid container using a twisting motion.
5. Squeeze the burette chamber to fill it with the desired volume of fluid (up to the marked capacity).
6. Allow the fluid to fill the chamber by opening the vent or releasing the clamp momentarily.
7. Close the burette clamp after the desired volume is reached.
8. Open the lower roller clamp to allow fluid to flow through the tubing and remove all air bubbles.
9. Close the clamp once the line is fully primed.
10. Connect the luer connector of the Measured Volume Set to the patient's IV access device (cannula or extension line).
11. Adjust the flow rate using the roller clamp as per the prescribed infusion rate.
12. Monitor the fluid level in the burette and refill as necessary without exceeding the marked capacity.
13. If Y-site is applicable, sterile syringe to inject through the Y site (ensure compatibility & prescription).
14. Dispose of the set after single use as per hospital protocol.

Intended Clinical Benefits to the patients:
1. Enables accurate dosing of medications in limited diluent volumes.
2. Automatic shut-off valve halts flow when chamber empties.
3. Microdrip system (60 drops/ml) supports fine flow control for intermittent therapy.
4. Transparent chamber with clear graduations facilitates real-time visual monitoring.
5. Single-use sterile design lowers infection transmission compared to reusable systems.

Clinical Safety:
1. Device Design and Material Safety.
2. Biocompatible products.
3. Our device is a single use device.
4. Our product is non-toxic, sterile & non-pyrogenic.

Performance characteristics:
1. Accurate and precise measurement of fluids due to a calibrated transparent chamber.
2. Controlled flow delivery enabled by a microdrip or macrodrip system with flow regulators.
3. Automatic shut-off valve to prevent air entry and over-infusion when the chamber is empty Sterile, disposable design reduces infection risk and improves clinical safety in infusion therapy.

Accessories which can be used with the device:
IV Cannula, Three Way Stop Cock, & other Infusion Devices.

Warnings:
1. The product should not be reprocessed.
2. Improper transport and handling may cause structural and/or functional damage to device or packaging.
3. Do not clean or resterilize.
4. Do not expose to heat or direct sunlight.
5. The product should be used immediately after opening the packaging.

MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.

Cautions:
1. Do not use if package is damaged.
2. Discard after single use.

Limitations:
The burette set is limited to gravity infusion, small-volume delivery, strict vertical positioning, single-use only, and is unsuitable for blood products, infusion pumps, or prolonged use to prevent dosing errors and infection risk.

Potential Side Effects:
1. Drug Toxicity.
2. Air Embolism.
3. Allergy respect to material.

Disposable instructions:
Used Devices may be contaminated with infectious and/ or other hazardous materials. Unused expired devices should be disposed of as per local regulations.

Duration of use:
Short-term duration (typically up to 72 hours).

Storage Conditions:
Store in a Cool & Dry Place.
Keep away from sunlight.
Temperature: +10°C to +40°C.

Shelf life:
5 Years.

Back Side:-

Type of Sterilization:
This device is sterilized by ethylene oxide gas. Do not re-sterilize, and do not reuse. Do not use it if the package is opened or damaged. Discard opened unused devices.

Notice to Users and/ or Patients:
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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)	CE 0123	CE Mark (CE Marking with Notified Body Number)
	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.)		Manufacturer (Indicates the medical device manufacturer) Manufacturing Unit: 525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India. Contact Details.: +91 8527589990 Fax No.: 0124 404 7533 Email ID: info@maisindia.com Website:www.maisindia.com
STERILE EO	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)	REF	Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)
STERILE EO	Single sterile barrier system (Indicates a single sterile barrier system)	LOT	Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)		Date of manufacture (Indicates the date when the medical device was manufactured)
	Do not re-use (Indicates a medical device that is intended for one single use only)		Use-by date (Indicates the date after which the medical device is not to be used)
	Keep dry (Indicates a medical device that needs to be protected from moisture)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	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)	EU REP	Authorized representative in the European Union / European Community (Indicates the authorized representative in the European Union / European Community OBELIS S.A. Boulevard Général Wahis 53, 1030 Brussels, Belgium Contact Number: +32(2)73 25 954 Email ID: regulatory@obelis.net Website: www.obelis.net
	Non-pyrogenic (Indicates a medical device that is non- pyrogenic)		Country of manufacture (To identify the country of manufacture of products)
UDI	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)	MD	Medical device (Indicates the item is a medical device)
	Latex free (Indicates a medical device that is Latex free)		Latex (Indicates a medical device that is Latex)
	Indicates product that does contain the phthalate plasticizers DEHP.		Contains or presence of phthalate plasticizers DEHP
10°c 40°c	Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed.		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)
	This way up		

CE 0123

EU REP **Obelis S.A.**
Boulevard Général Wahis 53, 1030 Brussels, Belgium.

Manufactured for:
Mais India Medical Devices Pvt. Ltd.
525-P, Sector-37, Pace City-II,
Gurgaon, Haryana-122001 (INDIA)

Neutral Code No.:GUJ/DEVICE/MFG/MD/2021/000042

EDITION: 02, **REV.:** 01_10.02.2026

REV BY	Q.A			
	Q.C			
	Pro.			
CHD BY	Mkt.			
DGN BY	Gopal Singh		DATE: 10.02.2026	
SCALE-N.T.S			TOLERANCE : ±2 mm	

MAIS INDIA MEDICAL DEVICES PVT. LTD.
525-P SECTOR-37, PACE CITY II,
GURGAON, HARYANA-122001 (INDIA)

TITLE : IFU of Burette Set / Measured Volume Set (M.V. Set)

For Party Code 000

COLOR OF PRINT: Black

SHEET No. 1/1

DRW. No.: I06001-IFU-000

EDITION: 02, **REV.:** 01

Size:- 225x130mm

APPROVED BY:

REVISION DETAILS:
Rev. 01: (i) The humidity limitation symbol has been removed and EC-REP has been changed to EU-REP and Symbol Updated.
(ii) The generic name “Measured Volume Fluid Administration Set (Burette Set)" has been replaced by “Burette Set / Measured Volume Set (M.V. Set)" and Overall IFU changes.