

INSTRUCTIONS FOR USE

FLOW REGULATOR

Indications

- For gravity-based controlled administration of intravenous fluids and parenteral solutions.
- For infusion of medicines, electrolytes, or nutritional fluids at adjustable rates.

Contraindications

- Do not use it for transfusion of blood or blood components.
- Not suitable for administration of highly viscous fluids.
- Avoid use in patients with known hypersensitivity to device materials.
- Not intended for neonatal infusion unless validated for such application.

Directions for Use

- Check the package integrity and product expiry before opening.
- Open the package and close the roller wheel or clamp on the infusion set, then remove the protective cap from the spike and insert the spike firmly into the fluid container.
- Ensure the flow regulator dial is in the "OFF" position and connect the flow regulator to the infusion set.
- Open the roller wheel or clamp of Infusion set and turn the flow regulator to the "Open" position.
- Purge/prime the set to expel all air, and once priming is complete, turn the flow regulator back to the "OFF" position.
- Connect the male luer connector of the flow regulator to the patient's IV access device. Ensure secure & leak-free connection.
- Open the flow regulator knob to the approximate desired rate, using the printed scale as a reference only, as it provides an indicative guide and the actual flow rate must be confirmed by drop counting.
- Immediately after setting the position, count the drops per minute in the drip chamber to confirm that the flow rate (mL/h) matches the required infusion rate.

Flow Rate Verification:

- To verify the flow rate, assume a standard drop factor of 20 drops per 1 mL unless otherwise specified by the infusion set manufacturer.
- Count the number of drops per minute in the drip chamber and compare this value with the required infusion rate in mL/h.
- For example, a prescribed rate of 60 mL/h corresponds to 1 mL/min, which equals 20 drops/min.
- If the observed drop count is higher than required (e.g., 25 drops/min), decrease the dial setting; if the drop count is lower (e.g., 15 drops/min), increase the dial setting. Recount drops for one minute after each adjustment.
- **Perform periodic re-checks:** Verify the drop count at least every 1–2 hours or as per institutional protocol.
- **Always re-confirm the drop count if any of the following occur:**
 - Replacement of fluid bag or a significant change in fluid level.
 - Patient repositioning, limb movement, or bed elevation.
 - Adjustment of the IV-Pole height or relocation of the infusion setup.
 - Change in ambient temperature or fluid viscosity.
 - Dispose of used sets per hospital protocol or local biomedical waste management rules.
 - Do not attempt to clean or reuse the flow regulator.

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Note: The printed scale on the flow regulator provides a guidance reference only. Actual flow may vary due to solution viscosity, temperature, pressure head differences etc. Always confirm drop rate manually.

Warnings

- For gravity infusion only. Do not connect to an infusion pump or syringes.
- Single use only. Do not reuse or re-sterilize. Reuse may cause infection, cross-contamination, or device malfunction.
- The device is supplied sterile via Ethylene Oxide.
- Do not use it if packaging is opened, torn, or damaged.
- Ensure all air is removed from the IV line before connecting to the patient to avoid risk of air embolism.
- The printed scale is indicative only, always verify drop count during the initial minutes of infusion.
- Improper use may result in inaccurate flow rate, under-infusion, or over-infusion.
- Discontinue use immediately if leakage, blockage, or flow inconsistency is observed.
- Monitor infusion flow rate periodically. Flow rate may vary due to patient position, solution viscosity, or height difference.
- Do not modify or alter the device.

Precautions

- Device should only be used by trained healthcare professionals or under their supervision.
- Do not connect to pressurized systems unless specified.
- Ensure compatibility between the flow regulator, Infusion set, and the type of solution infuse.
- Ensure correct gravity height difference between fluid source and patient for required flow rate.
- Adjust flow regulator slowly to avoid sudden surge of fluid.
- Avoid kinking, twisting, or compressing the tubing.
- Monitor infusion site frequently for signs of Infiltration/extravasation, Phlebitis or any Infection.
- Use aseptic technique during handling and setup.
- Do not store at temperatures outside 5°C to 35°C. Avoid exposure to excessive heat, moisture, or direct sunlight.
- Poly Medisure Limited shall not be liable for direct or consequential damages resulting from Reuse or re-sterilization, Incorrect handling or unauthorized modifications, Improper clinical use &/or non-compliance with instructions.



Cautions



See Instructions for use



Product reference/Art. No.



For single use only



Do not Resterilize



Do not use if packaging or product has been damaged or contaminated



Batch Number



Date of Manufacturing



Use by / Expiry date



Sterilised by Ethylene Oxide



Single Sterile Barrier System



European Authorised Representative



Manufactured by



Non Pyrogenic



Storage Condition



Keep Away from Sunlight



Keep Dry




Medical Device

 **POLYMED**

 **POLY MEDISURE LTD.**

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Not made with natural rubber latex
Not made with DEHP plasticizers

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