# IFU of Flow Regulator

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

**General Device Description:** The I.V. Flow Regulator is a sterile, single-use, gravity-fed device for manual control of intravenous fluid or medication flow rate. It features a calibrated dial or roller clamp to adjust resistance in the tubing, providing precise flow rates without external power.

**Principle of Operation:**

The I.V. Flow Regulator operates on the principle of manual mechanical flow resistance control. It functions within a gravity-fed infusion system, where the flow of intravenous fluid from an elevated container to the patient is regulated by adjusting the internal diameter of the tubing using a dial or roller mechanism.

The flow regulator dial compresses or expands the internal fluid pathway, thereby increasing or decreasing resistance to flow. This allows the user to select a predetermined flow rate (e.g., 5–250 mL/hr or 10-300 mL/hr) based on the calibration marked on the dial. The system maintains this rate as long as the relative height difference between the fluid source and the patient is stable, and there are no occlusions or air bubbles in the line.

The device does not require electricity or external power and is suitable for manual, low-risk, controlled infusions.

**Product Name:** I.V. Flow Regulator.

**Brand Names:** MAISFLOW™

**Variants:**

1. Flow Regulator (I.V. Flow Regulator with Y Injection site) **- GENERIC**
2. Flow Regulator (I.V. Flow Regulator with Y Injection site) - **MAISFLOW™**

**Intended Use:**

The Flow Regulator is intended to be used by qualified healthcare professionals for the controlled administration of intravenous fluids or medications into a patient's vascular system. It allows manual adjustment of flow rates to achieve accurate fluid delivery during infusion therapy. The device is designed for use in clinical, hospital, and emergency care settings and is suitable for adult and pediatric patients as per clinical judgment.

**Material of construction:**

Polyvinyl chloride (PVC), Acrylonitrile Butadiene Styrene (ABS) Polycarbonate (PC) & Is propene & Hi-density Polyethylene (HDPE)

**Indications:**

The I.V. Flow Regulator is indicated for use in patients requiring precise and controlled administration of intravenous fluids or medications. It is suitable for use in the following situations:

- General fluid and electrolyte therapy
- Intravenous medication infusions requiring controlled flow
- Pediatric or geriatric infusions where accurate flow control is critical
- Non-pressurized gravity-based infusion systems
- Situations where infusion pumps are not available or necessary

**Contra-indications:**

The I.V. Flow Regulator should not be used in the following conditions:

- Administration of blood or blood components, unless the device is specifically validated for such use.
- Infusion of high-viscosity fluids (e.g., parenteral nutrition, contrast media) with standard variants not designed for such applications.
- Use in pressurized infusion systems or with infusion pumps, as the device is designed for gravity-fed systems only.
- Patients with hypersensitivity or known allergy to any material of the device (e.g., polyvinyl chloride or other polymers used).
- Situations requiring automated or highly accurate volumetric control, where an electronic infusion pump is indicated.

**Intended Patient Population:**

The I.V. Flow Regulator is intended for use in adult, pediatric, and geriatric patients who require intravenous fluid or medication administration through a gravity-fed I.V. system.

Patient selection is based on the clinical judgment of qualified healthcare professionals, considering:

- The patient's medical condition requiring fluid therapy or drug infusion
- The patient's vascular access status
- The need for controlled, manual adjustment of flow rate

The device is not restricted by gender or ethnicity and is suitable for both inpatient and outpatient care settings.

**Intended User:**

Qualified doctor or a paramedic

**Use environment:**

Proper healthcare setup

**Size specifications:**

| Flow Regulator | | |
|---|---|---|
| **Length** | **I.D.** | **O.D.** |
| Tube length 40 cm | 3.0±0.1 | 4.0±0.1 |

| Flow Regulator | | |
|---|---|---|
| **Flow Rate** | | |
| Flow Regulator | Flow Regulator with 250 mL/hr | ±15% |
| Flow Regulator | Flow Regulator with 300 mL/hr | ±15% |

**Instruction for use:**

Follow aseptic techniques throughout device handling.

**1. Preparation**

·Verify the packaging is intact and sterile. Do not use if the pouch is damaged or opened.

·Check the expiry date printed on the packaging.

**2. Priming**

- Connect the proximal (inlet) end of the I.V. Flow Regulator to the I.V. fluid container (bottle or bag).
- Slowly open the regulator dial to allow fluid to fill the tubing and eliminate air bubbles.

**3. Connection to Patient**

- Connect the distal (outlet) end to the I.V. catheter or administration set port using the Luer Lock or Slip connector.
- Ensure all connections are secure to prevent leakage or disconnection.

**4. Flow Rate Adjustment**

- Use the flow control dial or roller clamp to adjust the desired flow rate.
- Flow rates are marked on the dial (e.g., 10, 50, 100, 250 mL/hr). Select appropriate setting based on clinical need.

**5. Monitoring**

- Periodically check for:
  - (a) Correct drip rate
  - (b) No air in the line
  - (c) No kinks or occlusions in tubing
  - (d) Secure connections

**6. Post-Use**

· Once infusion is complete, close the dial fully to stop flow.

· Disconnect from the patient and dispose of the device in accordance with biohazard waste regulations.

**Intended Clinical Benefits to the patients:**

The intended clinical benefit of the I.V. Flow Regulator is to enable precise and consistent control of intravenous fluid and medication delivery, ensuring safe, effective, and controlled therapy for patients. By allowing adjustable flow rates without the need for electronic infusion pumps, it supports reliable treatment in diverse clinical settings, reduces infusion-related complications, and enhances overall patient care during fluid or drug administration.

**Clinical Safety:**

- Biocompatible products.
- Our device is a single use device.
- Our product is non-toxic, sterile & non-pyrogenic.

**Performance characteristics:**

Flow Regulator should be easy to manipulate, allowing for efficient switching between lines without leakage or interruption of flow, ensuring compatibility with various infusion sets, catheters, and monitoring equipment is crucial to prevent compatibility issues and ensure seamless integration into clinical workflows., Facilitate more than one infusion through single I.V. access by controlling flow direction and compatible for connection with standard 6% luer device.

**Accessories which can be used with the device:**

Flow Regulator can used along with the connecting accessories such as I.V. Cannula and other infusion devices.

**Warnings:**

1. The use of this product is restricted to a qualified doctor or a paramedic.
2. Read instructions before use.
3. MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.
4. The product should not be reprocessed.
5. Visually inspect and carefully check the product and packaging before use.
6. Improper transport and handling may cause structural and/or functional damage to device or packaging.
7. The product is non-toxic, sterile & non-pyrogenic.
8. Do not Clean or resterilize. For single use only. Discard after use.
9. Re-use of single-use devices creates a potential risk (i.e, Bloodstream infection) of patient or user.
10. If the device is reused, then it may cause bacterial infection to the patient, and also may lead to contamination and/or impairment of functional capability which may in turn lead to injury to the patient.
11. After withdrawal, do not reintroduce the steel needle into the catheter, as the latter may be cut off, leading to catheter embolism.
12. If there is any change in expected performance of the device or in case of any malfunction the device should be immediately removed & sent back to supplier for analysis.
13. Store in a cool & dry place.
14. Do not expose to heat or direct sunlight.
15. The product should be used immediately after opening the packaging.

**Cautions:**

Do not use if the package is Open or damaged.

Discard after single use.

**Limitations:**

Fluid Leakage and Cross-Contamination

**Potential Side Effects:**

·Using Flow regulator for an extended period of time can increase the risk of Infection.

·The use by more than one patient may cause a cross-infection.

·Do not use the product if it is polluted, dirty or evidently deteriorated.

**Disposal Instructions:**

Disposing of Flow Regulator, should be done in accordance with Hospital waste disposal regulations and guidelines. The used device should be disposed of as 'hospital contaminated waste' – typically incinerated or as per safe hospital practices as improper disposal can lead to bio-hazard.

**Duration of use:**

Short-term duration (Normally intended for continuous use for between 60 minutes and 30 days) [Note : Generally, to be used for up to 72 hours for best performance].

**Storage Conditions:**

Store in a Cool & Dry Place. Keep away from sunlight
Temperature: 10º to 40º C
Humidity: 50 ± 10%

**Shelf life:** 5 Years

**Life Time**

Once Uses started, the device shall be used for up to 72 hours for the best performance.

**Type of Sterilization:**

ETO sterilization

**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) |  | Latex free (Indicates a medical device that is Latex free) |
|  | 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) |

| Symbols | Title of the Symbol | Symbols | Title of the Symbol |
|---|---|---|---|
|  | 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) |
|  | 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) 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 |
|  | Keep dry (Indicates a medical device that needs to be protected from moisture) |  | 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 |
|  | 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. |
|  | Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified) |  | Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully) |
|  | Indicates product that does contain the phthalate plasticizers DEHP. |  | This way up |


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

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



**EDITION:** 02, **REV.:-** 00_29.08.2025