Front Side:-

IFU of Flow Regulator

Manufactured by Mais India Medical Devices Pvt. Ltd.

General Device Description: Flow Regulator is a sterile, single-use, non-pyrogenic medical device designed to provide precise, manual control over the flow rate of intravenous (IV) fluids delivered to a patient. It is typically used in gravity-fed IV systems and enables healthcare providers to accurately adjust and maintain the desired flow rate without the need for complex electronic infusion pumps. The device incorporates a flow control mechanism, a dial which is marked with flow rate indicators in millilitres per hour (mL/hr). This allows for fine-tuned regulation of fluid delivery based on the clinical requirements prescribed by the attending medical professional.

Product Name: Flow Regulator.

Brand Names: MAISFLOW™

Variants:
Flow Regulator (I.V. Flow regulator with Y injection Site)

Intended Use:
Flow Regulator is a medical device that incorporated between infusion line and indwelling Venipuncture device by a male and a female Luer lock connector to regulate the flow of IV Fluids through flow regulator.

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

Indications:
Flow regulator is indicated for use in patients requiring precise and controlled administration of intravenous fluid and medication.
It is suitable for use in following situations:

- Use to regulate the flow rate of standard IV solutions in non-pressurized gravity-based infusion system.
- Use to control the administration of intravenous drugs at specific, controlled intervals.
- Situations where infusion pumps are not available or necessary.

Contra-indications:
- Do not use in patients with known allergy or hypersensitivity to any of the materials listed.
- Not suitable for the administration of highly viscous fluids.
- Not intended for blood transfusions.

Intended Patient Population:
Flow Regulator can be used for patients of all ages, including neonates, children, adults.

Intended User:
Qualified doctor or a paramedic.

Use environment:
Proper healthcare setup.

Size specifications:

Flow Regulator		
Length	**I.D.**	**O.D.**
Tube length 20 cm	3.0±0.1	4.0±0.1
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:
1. Sanitize your hands with an alcohol-based cleanser.
2. Verify the integrity of the package and confirm that the device is within its expiration date.
3. Remove the flow regulator from package using aseptic technique.
4. Connect flow regulator input to IV set/infusion line and output to IV access device.
5. Ensure all connections are secure and tight.
6. Prime the infusion line ensuring that no air remains in the system.
7. Adjust the Flow Regulator to achieve the desired IV fluid flow rate. The markings on the device indicate the flow rate in millilitres per hour (mL/hr).
8. Release the clamp of IV set/infusion line and monitor the drip chamber and the patient to ensure the fluid is flowing correctly and the patient is tolerating the infusion.
9. Begin infusion and continuously monitor the flow rate and patient condition.
10. As required, disinfect the Y-site injection port and administer secondary medication.
11. Once the infusion is complete, carefully disconnect the regulator and dispose of it, along with the other IV tubing, in the appropriate medical waste container. Do not reuse single-use devices.

Intended Clinical Benefits to the patients:
- Allowing precise and consistent control of fluid or medication.
- The dial allows for easy, repeatable flow rate adjustments, reducing reliance on manual roller clamps and minimizing the risk of human error.
- Biocompatible products.

Clinical Safety:
- Biocompatible products.
- Our device is a single use device.
- Our product is non-toxic, sterile, Latex Free, DEHP free & non-pyrogenic.

Performance characteristics:
Flow Regulator is a medical device reliably delivers intravenous fluids at precisely controlled flow rates, as adjusted by the healthcare professional, ensuring accurate administration of prescribed volumes.
While cost-effective and easy to use, the device's manual adjustment mechanism provides real-time control over fluid flow, allowing rapid response to clinical needs. Constructed from biocompatible, non-toxic, and non-pyrogenic latex Free materials, it minimizes the risk of adverse patient reactions.

Accessories which can be used with the device:
Flow Regulator is used along with the connecting accessories such as I.V. Cannula and other infusion/IV access devices.

Back Side:-

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 its packaging.
7. The product is non-toxic, sterile & non-pyrogenic.
8. Do not clean or re sterilize. 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 a bacterial infection in patient, and also may lead to contamination and/or impairment of functional capability, which may lead to patient injury.
11. 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 analysis.
12. Store in a cool & dry place.
13. Do not expose to heat or direct sunlight.
14. The product should be used immediately after its packaging is opened.

Cautions:
Do not use if the package is Open or damaged.
Discard after single use.

Limitations:
Do not use with highly viscous fluids.

Potential Side Effects:
- Patients with hypersensitivity to any of the device materials may experience localized skin irritation or allergic responses.
- Improper use or reuse of the single-use device can increase the risk of bloodstream infections due to contamination.
- Misadjustment or device malfunction could lead to over-infusion or under-infusion, potentially causing fluid overload, dehydration, or inadequate drug delivery.

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: 10° C to 40° C.

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)	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

Symbols	Title of the Symbol	Symbols	Title of the Symbol
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)
	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
	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)
	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	Latex free (Indicates a medical device that is Latex free)	10°c 40°c	Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed.
NOT DEHP	Indicates product that does contain the phthalate plasticizers DEHP.		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)
	This way up		

Manufactured by:
Mais India Medical Devices Pvt. Ltd.
525-P, Sector-37, Pace City-II,
Gurgaon, Haryana-122001 (INDIA)
Mfg. Lic. No.: MFG/MD/2019/000037

CE 0123
EU REP **Obelis S.A.**
Boulevard Général Wahis 53, 1030 Brussels, Belgium.

EDITION: 02, **REV.:** 01_04.02.2026

REV BY	Q.A				**TITLE : IFU of Flow Regulator**
	Q.C				**For Party Code 000**
	Pro.				
CHD BY	Mkt.				**COLOR OF PRINT:** Black
DGN BY	Gopal Singh			DATE: 04.02.2026	
SCALE-N.T.S				TOLERANCE : ±2 mm	

SHEET No. 1/1

DRW. No.: I09001-IFU-000

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

Size:- 225x130mm

APPROVED BY:

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

REVISION DETAILS:
Rev.: 01 (i) The humidity limitation symbol has been removed. (ii) EC-REP has been changed to EU-REP. (iii) Overall, some changes have been made to the IFU, such as to the Instructions for use and Warnings.