Prymax PM

Flow Regulator Line

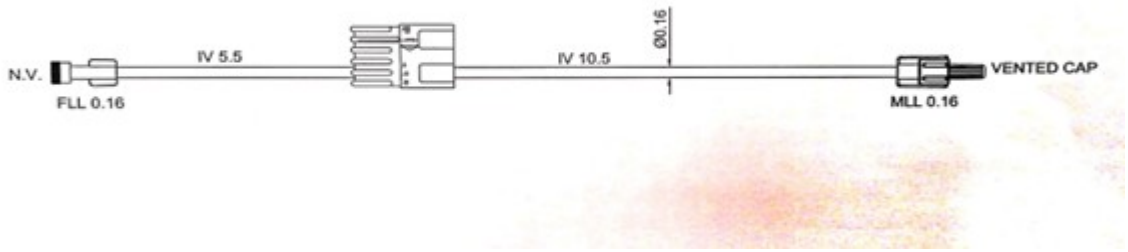
DEVICE DESCRIPTION:

The flow regulator line is vital in infusion therapy, ensuring secure and accurate medication delivery to patients. Flow regulator line to regulate the flow of intravenous fluids and medicines at a particular rate. It assists in streamlining the specific dosage levels and avoids over-administration. It is pre-calibrated in ml/hour count. The flow can be controlled from OFF position (0 ml/hour) to 300 ml/hour & "Y" injection port (latex) is also provided in the line for intermittent medication.

Available variants:

Model Number	Description/Contents
PFR-01	Flow Regulator line
PFR-Y01	Flow Regulator line with Y Injection Port
PFR-Y02	Flow Regulator line with Y Injection Port & Infusion set

Drawing of product:



MATERIAL USED:

Poly Vinyl Chloride, Poly propylene, Poly carbonate, Acrylonitrile butadiene styrene (ABS)

INTENDED PURPOSE:

INTENDED USE: To be used to control the amount of IV solution infused in to the body.

INTENDED USER: The device is intended to be used only by a qualified medical professional

INTENDED PATIENT POPULATION: All patient population irrespective of age and gender

Prepared by:	Approved By:

INDICATIONS:

- Graduated infusion of I.V. solutions
- Intravenous drugs administration
- Total parenteral nutrition (TPN)

CONTRAINDICATIONS:

Use in patient with a known allergic reaction to any of the product components, Administration of highly viscous fluids, It is not intended for the delivery of whole blood, blood components.

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS:

Clinical Benefits:

- User can control necessary amount of solution by looking at marking range and setting it as per requirement. It is pre-calibrated in ml/hour count. The flow can be controlled from OFF position (0 ml/hour) to 300 ml/ hour. Injection port Y is also provided in the line for additional drug injection.

Performance Characteristics:

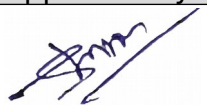
- Flow rate
- Accuracy
- Ease of use

INSTRUCTION FOR USE:

- Open the product in sterile environment.
- Visually inspect the product & packing for any visual defects. Improper transportation & handling can cause structural/functional damage to the device or packaging.
- Make sure that the dial is set to OFF.
- Connect the Male Luer Lock of flow regulator line to IV set or Spike and connect it to fluid container such that fluid level is approximately 80cm to 90cm (3 ft) above the needle / patient.
- Remove air from IV line by setting dial to open.
- Turn the dial to set the desired flow rate in ml/hour.
- Adjust the dial as per requirement or for minor adjustments

WARNINGS & PRECAUTIONS:

- Do not use the product if the package is damaged or open.
- The procedure must be performed by trained personnel, well versed in anatomical landmark, trained for safe Techniques and aware of potential complications.
- Product must not be re-sterilized. The re-sterilization of the device will alter mechanical and chemical properties, inappropriate of intended use and also increase the EO residue on device.
- Sterile, Single use: Do not reuse, reprocess or resterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death

Prepared by:	Approved By:
	

ADVERSE EFFECTS:
Possible complications associated with the device include Insufficient flow, Obstruction of flow and air in device.

RE-USE HAZARDS:
Transmission of infection from one patient to another.

PACKAGING:
The device is packed in paper pouch, which is further packed in inner carton & master carton.

STERILIZATION:
Device is EO sterilized, and sterilization is done in-house.

STORAGE CONDITION:
Temperature Limit: 15^{o}C to 40^{o}C.

COUNTRY CODE: -356

DEVICE SHELF LIFE: 3 Year

DISPOSAL
After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal law and regulation.

REPORTING OF ADVERSE EVENTS:
In case of any serious adverse event please report the same to info@prymaxhealthcare.com & gloizou@compliancems.com.au.

Note: For product used in EU also report to the competent authority of the Member State in which the user and/or patient is established.

GOODS RETURN POLICY
Refer to the company's return goods policy.
Please contact the branch office or customer service at info@prymaxhealthcare.com or call +91 129 4011818.

SYMBOLS USED ON PRODUCT LABEL

Lot number


Do not re-use

Sterilized by Ethylene Oxide


Manufacturing date


Use-by date


Caution

Prepared by:	Approved By:

Non-pyrogenic

Do not resterilize

Catalogue number

Manufacturer

Storage Temperature Range

Conformité Européenne

Do not use if package is damaged and consult instructions for use

Consult Instructions for Use

Single Sterile Barrier System

Medical Device

UDI Carrier

Country of Manufacturer

Manufactured By:

Prymax Healthcare LLP.,
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Haryana, INDIA -121001
gloizou@compliancems.com.au
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