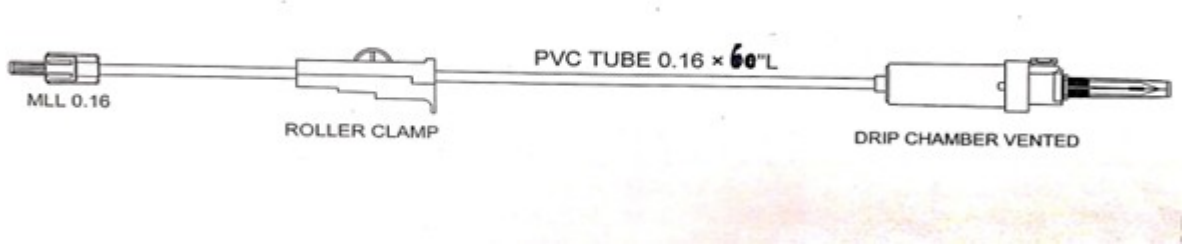
Prymax PM

Infusion Set

DEVICE DESCRIPTION:

Device Contains Flow regulator with extension set for precise flow control. Ensures safe application in demanding critical care settings. Reliable Drop Rate accuracy across the full adjustable scale. Ergonomic dial design with ridges for easy grip and adjustment. Precise Drop Rate control of IV fluids with range of 5ml/hr to 250 ml/hr. DEHP Free soft and kink resistant PVC tubing. Male luer connector at one end and female luer connector at other end. Provided with a latex free"Y" type injection port for intermittent medication. Can be used with all standard I.V sets using luer lock connections. Sterile and individually packed.

Drawing of product:



MATERIAL USED:

Poly Vinyl Chloride (PVC), Polypropylene, Polycarbonate, Acrylonitrile Butadiene Styrene

INTENDED PURPOSE:

INTENDED USE: Infusion set or IV set is used to administer IV solution to the body through veins.

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

INDICATIONS:

Infusion sets are used for the controlled infusion of medications, typically over long periods of time. IV sets are used to connect the medication to the needle inserted into the patient. IV extension sets are also used to extend IV lines without risk of contamination.

Prepared by:	Approved By:

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:
The benefits of infusion therapy include:

- Fast-acting relief, especially in emergency situations, like after an allergic reaction or during childbirth
- Medication for those who cannot take pills orally
- Administering larger and/or controlled amounts of medication
- Intramuscular and subcutaneous injections help drugs remain in the body longer
- High success rates for several conditions

Performance Characteristics:

- Controlled flow rate
- Piercing of spike

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.
- Check the packing carefully, if packing is found damaged, torn or pierced, discard the piece.
- Wash-up and scrub hands and preferably use pre-sterile protective gloves.
- Peel / Tear open the pouch and take out the device aseptically. Close flow regulator.
- Insert the spike at the top of the bottle to its full Length into the top of the solution container.
- Squeeze drip chamber till it is half filled.
- Removing prime stop connector from rotating luer locks connector & allow solution to pass until all air bubbles in the tube are removed. Close the flow regulator.
- connect the set to intended device and regulate desired flow rate by using flow regulator

WARNINGS & PRECAUTIONS:

- The device will perform as intended when the instructions are

followed accordingly.

- Examine individual package for integrity prior to use. If packaging has been damaged, do not use.
- Any used IV set considered contaminated. Discard all used sets together with the holder in biohazard containers approved for their disposal.
- Do not use for subcutaneous infusion or injection.
- A reuse of the product may cause harmful infections, injury or death.
- Gloves should be worn at all times during venipuncture to minimize exposure hazard.
- Avoid blood leakage and any air in the tubing during infusion procedure.
- Make sure all air is removed by priming prior to use as IV infusion device.
- Product must not be resterilized. 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

ADVERSE EFFECTS:

Malfunction due to leakage or blockage, Embolism, Allergic reactions, tissue necrosis, Phlebitis, Thrombophlebitis & blistering Phlebitis, Infiltration, Hematoma, Extra Vascular drug administration.

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: 5 Year

DISPOSAL

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	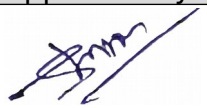

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal law and regulation.

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


Non-pyrogenic

Do not resterilize

Catalogue number


Manufacturer

Storage Temperature Range

Conformité Européenne


Do not use if package is damaged


Consult instructions for use


Single Sterile Barrier System

Medical Device

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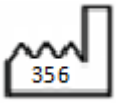

UDI Carrier
Manufacturer

Country of

Manufactured By:

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