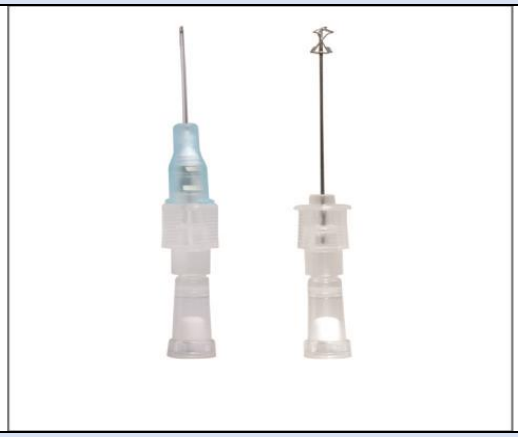
Instruction for use (IFU)

IV. Cannula with Safety Features

Sizes: 14-26G

8 9 0 3 1 7 2 S I V C 8 U

Basic UDI-DI

IV Cannula With wings & with Port		
	PRIMAFLON SAFETY™ (Ref. Art. No. IT0129)	**LA-MED SAFETY®** (Ref. Art. No. IT0133)
IV Cannula Without wings & without Port		
	PRIMACAN ALPHA SAFETY® (Ref. Art. No. IT0128)	**PRIMAPEN SAFETY®** (Ref. Art. No. IT0132)
IV Cannula with small wings and without Port		
	PRIMANEO SAFETY® (Ref. Art. No. IT0131)	

SCOPE:

This IFU is applicable to the IV cannula with safety feature manufactured by La-med Healthcare Pvt. Ltd. Faridabad, Haryana, India.

INTENDED USE:

The IV Cannula with safety feature is a passive device to provide for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of vascular access devices. It is a device through which fluid is introduced or withdrawn from the human circulation system, through a catheter.

MATERIAL OF CONSTRUCTION/USED:

PTFE/ FEP, PUR, Polypropylene, Polythene, Stainless steel, Polyacetal.

INDICATIONS:

- Infusion of I V Fluid
- Infusion of I V Drugs administration
- Transfusion of blood/blood components
- To deliver the fluid to the patient who is unable to take it orally
- Blood Sampling

CONTRAINDICATIONS:

- Administration of highly viscous fluid.
- Large blood transfusion.
- IV cannulation is contraindicated in patients with oedema.
- IV cannulation is contraindicated at sites close to infection.
- Not to be used in patients with known hypersensitivity to any of the materials used.
- Administration of fluid or drugs that are irritant to the materials of the product.

KNOWN CHARACTERISTICS OF DEVICE IN CASE OF RE-USE:

- After ejecting the needle from the catheter, the Safety clip covers the bevel of the needle to prevent Needle stick Injury.
- Difficult to penetrate the needle during use and probability of fold back of catheter
- Any infectious disease can transfer

WARNINGS:

- Visually inspect and carefully check the product and packaging before use. Improper transport and handling may cause structural and/ or functional damage to the device or packaging.
- The product is guaranteed non-toxic, sterile & non- pyrogenic if the package has not been opened or damaged.
- For single use only.
- Do not use if components are damaged, deformed, or missing.
- Do not overtighten. Do not proceed if resistance is felt or interaction between components is failing.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and country laws and regulations.
- **Don't re-sterilize the device**: Re-sterilization of the device will have a detrimental effect on its known properties thereby rendering it inappropriate for the intended use.
- **Don't re-use the device**: Re-use of the device may lead to infection, illness/injury.
- The product should not be reprocessed.

- The product should be used by a doctor/ Registered practitioner or Paramedic.
- Rear end and Port (wherever applicable) of I.V. Cannula with safety feature having 6% female taper as per EN 80369-7 for the attachment with the respective device.
- Do not try to reinsert a partially or completely withdrawn needle.
- Do not use any scissors or cutting other tools to remove the IVC fixing (plaster etc)

POTENTIAL COMPLICATIONS:

- Local infections
- Venous thrombophlebitis
- Extravasation of infused fluids into surrounding tissues
- Arterial puncture
- Hematoma or bleeding
- Damage to the vein
- Nerve damage
- Air embolism
- Catheter embolism

PRECAUTIONS:

- Do not use if sterile pouch is opened & damaged.
- Do not attempt to re-sterilize this device. Re-sterilization on this product has not been validated.
- The device must be used by medical professionals only.
- Hand hygiene and barrier precautions (such as latex or non-latex gloves) during IV cannulation minimize the risk of infection.
- Use an upper extremity site in preference to one on a lower extremity for cannula insertion. Transfer a cannula inserted in a lower extremity site to an upper extremity site as soon as the latter is available.

MODE OF ACTION:

Intravenous (IV) cannulation is a technique in which a cannula is placed into a patient's vascular system to administer medicaments or fluids intravenously.

PREPARATION FOR DECONTAMINATION:

Skin preparation using alcohol in 2% chlorhexidine is the preferred solution for dressings.

SYSTEM PREPARATION:

- Check the label for manufacturing and expiry dates (do not use the medical device after expiry)
- Check for UDI number
- Make sure the package is not damaged.
- Visually examine the device to see if there are any damages.

INSTRUCTIONS FOR USE:

➢ **Preparation**

- Select and prepare site according to facility protocol
- Completely remove the paper from the packaging.
- Remove protective the cover by holding it at each end, then pull it straight apart.
- Do not rotate the catheter prior to insertion
- Confirm catheter hub is seated tightly against flashback chamber.

- **Perform insertion**

- Hold skin taut, insert the catheter at the optimal insertion angle
- Visualize the first flashback in the flashback chamber to confirm needle entry in the vessel.
- Upon first flashback visualization, LOWER and advance the needle and catheter together approx 3 mm to ensure the catheter tip is in the vessel.

- **Thread catheter**

- Hold the needle still, advance the catheter off the needle and visualize the second flash within the catheter to confirm the catheter is in the vessel.
- After confirmation, continue advancing the catheter of the needle into the vessel.
- Release tourniquet.

- **Occlude vessel and stabilize catheter hub**
- **Remove the needle from the catheter**

- With hub stabilized, swiftly remove needle straight out from the hub.
- The passive safety shield automatically covers the needle bevel.
- Properly discard the needle into the sharp container.

- **Connect and secure catheter**
  - Immediately CONNECT and TIGHTEN the accessory device to the catheter hub.
  - Stabilize and dress the site per facility protocol.
  - **ALWAYS REMEMBER** Never reinsert the needle into the catheter; catheter shearing may occur and may cause embolism. In the case of an unsuccessful IV start, remove the stylet first to activate the safety mechanism, then remove the catheter from the patient.
  - Do not use any scissor or cutting other tools to remove the IVC fixing (plaster etc)

DEVICE DISPOSAL SYSTEM:

Discard the needle in proper waste container & dispose off the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste

Intended Patent Population (TARGET AGE GROUP):

These catheters may be used for any age group with consideration given to adequacy of vascular anatomy and appropriateness of the procedure.

Demographic Category	Patient Population
Age (Pediatrics)	Neonates: From birth to first 28days of life, Infants: 29days to less than 2years Children: 2years to less than 12years Adolescent: Aged 12 through 21years (upto but not including 22nd birthday)
Age (Adults)	Young: 21years to 35years Middle: aged 36years to 55years Older: Aged older than 55years
Sex	Male & Female

DURATION OF USE: 36 hours

It is recommended to withdraw the I.V. cannula with safety feature after 36 hours from the patient. The user is accountable for any type of problem taking place in case of use after 36 hours of the same device.

STORAGE CONDITION:

Temperature: 10 to 40^{0}C and Humidity: 60±5%

SHELF LIFE OF DEVICE:

Based on the stability study & internal testing for sterile products, the shelf life of the products is recommended for 5 years from the date of sterilization/manufacturing. The product life is mentioned on the product label.

RETURN OF DAMAGED PRODUCT:

Return the products in its original box identified by the LOT number, your purchase reference and reason for the return. The action shall be initiated to handle the product record as per the law of the land (IMDR 2017 under Drug and Cosmetic act 1945) and in compliance of the regulatory requirement of the destination of the product. The product recall procedure will be followed for the handling of this situation.

PACKAGING:

The device is supplied in a blister pack/ribbon pouch, along with IFU, inner labels in a duplex box and with external identification labels.

NOTICE FOR USER / OR PATIENT:

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.

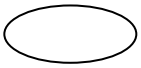
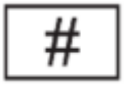
The instructions provided above have been validated by the manufacturer of the medical device as being **CAPABLE** of preparing a medical device for safe use.

STERILIZATION & EXPIRY DATE:

The device is sterilized by Ethylene Oxide (EO) & expiry date is 5 years from the date of manufacturing.

ELECTRONIC VERSION OF IFU: Please follow the link below to download the electronic version of IFU:
https://lamed.healthcare/download/

Explanation of Symbols:

Symbol	Meaning	Symbol	Meaning
	Lot Number/ Batch Number		Sterilization by Ethylene Oxide
	Caution		Use Until (YYYY-MM)
	Don't use when packing damaged		Non-Pyrogenic
	Do not reuse		Do not re-sterilize
	Keep away from sunlight		Keep dry
	Temperature limit		Manufacturer
	Country of Manufacturer		CE Mark
	Single Sterile Barrier System		Medical Device
	Latex Free		Unique Device Identifier
	Date of Manufacture		Consult instructions for use or consult electronic instructions for use
	Catalogue number		Model Number
	Importer		Distributor
	DEHP Free		Authorized representative in the European Community European Union
	Country Code		

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