INSTRUCTION FOR USE
(Infusion Set)

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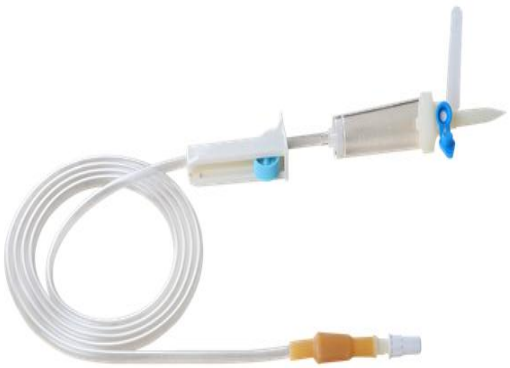
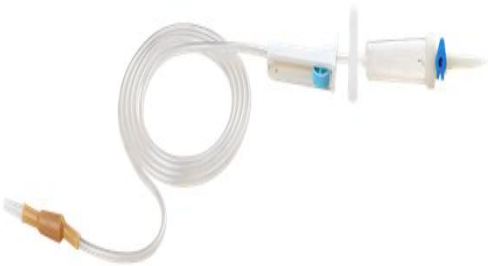
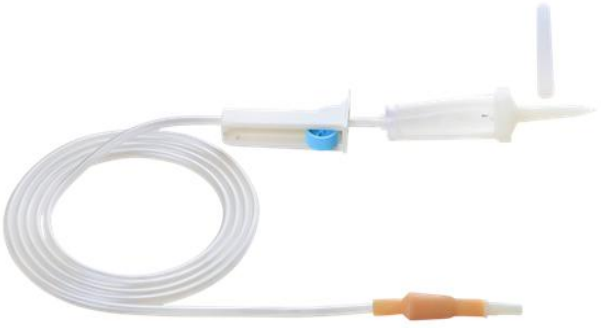
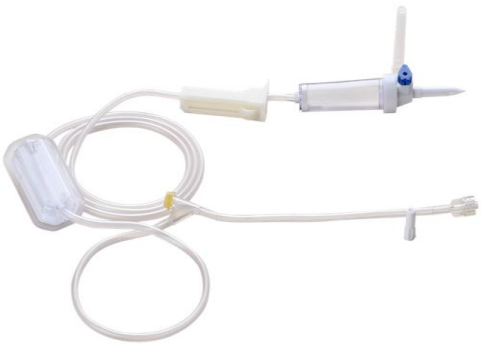
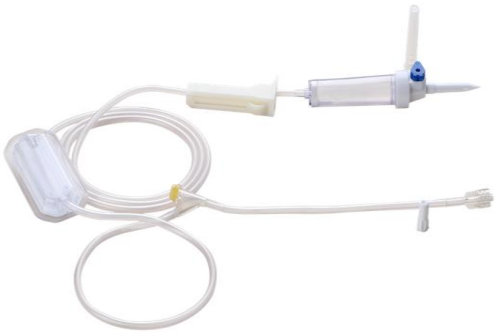
INSTRUCTION FOR USE CONTAINS THE INFORMATION ON HOW TO USE THE INFUSION SET

Infusion Set with or without air-vent		
	DRIPPY ®V (Ref. Art. No. IT0501-01)	**DRIPPY® NV** (Ref. Art. No. IT0501-04)
Infusion Set with or without air-vent and with microneedle and drip chamber		
	DRIPPY ® MICRO V (Ref.Art.No.IT0501-06)	**DRIPPY ® MICRO NV** (Ref.Art.No.IT0501-07)
Infusion Set with air vent and 0.2 micron filter		
	ONCO GUARD ® (Ref. Art. No. IT0501-11)	**ONCOGUARD ® PLUS** (Ref. Art. No. IT0501-26)

SCOPE:

The Instruction for use contains the information on how to use the Intravenous Infusion Set and its variants detailed in below tabulation, manufactured by La-med Healthcare Pvt. Ltd.

S. No	Product Variants/ Models	Components Description	Trade/ Brand Name	Product Ref. Art/ Catalogue Ref. No.
1.	Infusion Set with air vent	Without Hypodermic Needle	Drippy® V	IT0501-01
		With Hypodermic Needle	Drippy® V	IT0501-02
		Without Hypodermic Needle with Y-Site & Luer Lock	Drippy® V	IT0501-05
		With Hypodermic Needle with Y-Site & Luer Lock	Drippy® V	IT0501-46
		With Hypodermic Needle with Y-Site & Luer Lock	La-med®	IT0501-09
		Without Hypodermic Needle with Needle Free Y-Site & Luer Lock	Drippy® V	IT0501-40
		With Hypodermic Needle, large drip Chamber, Y-Injection Site, Rotating Luer Lock	Drippy® ultra	IT0501-25
		Without Hypodermic Needle, with Rubber bulb & Protective Cap	La-med®	IT0501-47
		With Hypodermic Needle, Rubber bulb & Protective Cap	La-med®	IT0501-48
		Without Hypodermic Needle, with Rubber bulb & Protective Cap	Endure IV Set	IT0501-49
		With Hypodermic Needle & Rubber bulb	Endure IV Set	IT0501-50
		Without Hypodermic Needle, with Rubber bulb & Protective Cap	Niche	IT0501-51
		With Hypodermic Needle & Rubber bulb	Niche	IT0501-52
2.	Infusion Set without air vent	With Hypodermic Needle & Rubber bulb	Drippy® NV	IT0501-03
		Without Hypodermic Needle, with Rubber bulb & Protective Cap	Drippy® NV	IT0501-04
		With Hypodermic Needle & with rubber bulb	Drippy® NV PRO	IT0501-36
		With Hypodermic Needle & with rubber bulb	La-med®	IT0501-53
		Without Hypodermic Needle, with Rubber bulb & Protective Cap	La-med®	IT0501-54
		With Hypodermic Needle & with rubber bulb	Endure IV Set	IT0501-55
		Without Hypodermic Needle, with Rubber bulb & Protective Cap	Endure IV Set	IT0501-56
		With Hypodermic Needle & with rubber bulb	Niche	IT0501-57
		Without Hypodermic Needle, with Rubber bulb & Protective Cap	Niche	IT0501-58

3.	Infusion Set with air vent and with micro needle & Drip Chamber	With Hypodermic Needle & Rubber bulb	Drippy® Micro V	IT0501-06
		With Hypodermic Needle, Y-Injection Site & Luer Lock	Drippy® Micro V	IT0501-18
		With large drip chamber, Hypodermic Needle, Y-Injection Site & Luer Lock	Drippy® ultra- micro	IT0501-27
		With Hypodermic Needle & Rubber bulb	Endure IV Set	IT0501-59
		Without Hypodermic Needle & with Rubber bulb	Endure IV Set	IT0501-60
		With Hypodermic Needle, Y-Injection Site & Luer Lock	Endure IV Set	IT0501-61
		Without Hypodermic Needle, with Y-Injection Site & Luer Lock	Endure IV Set	IT0501-62
4.	Infusion Set without air vent and with micro needle & Drip Chamber	Infusion Set without air-vent and with micro-drip Set and Hypodermic Needle	Drippy® Micro NV	IT0501-07
		With Hypodermic Needle, Y-Injection Site & Luer Lock	Endure IV Set	IT0501-63
		Without Hypodermic Needle, with Y-Injection Site & Luer Lock	Endure IV Set	IT0501-64
5.	Infusion Set with air vent and 0.2 micron filter	With Hypodermic Needle, Y - injection site, Luer lock and 0.2µ filter	Onco Guard®	IT0501-11
		With Needle free Y- Injection Site, Combi lock and 0.2µ filter	Onco Guard Plus	IT0501-26
		With Needle free Y- Injection Site, Combi lock and 0.2µ filter	Endure Onco Set Plus	IT0501-30
6.	IV Infusion Set Premium with air vent and dual drip chamber	With Hypodermic Needle, Y-Injection Site & Rotating Luer Lock	Transfix™ IV	IT0501-28

IMPORTANT INFORMATION YOU NEED TO KNOW BEFORE USE OF INFUSION SET

INTENDED USE:
The Infusion Sets are used to administer Intravenous fluid and/or electrolytes into the human circulating system by using an intravenous catheter or cannulae.

INTENDED USER OF THE DEVICE:
The intended user of the device is a qualified doctor, healthcare professional, and trained medical staff (Paramedics, emergency room staff, critical care staff, and operating room personnel).

- **Education and Experience:** The product should be used only by qualified doctors or paramedics who are experienced and have a thorough understanding of the clinical and technical aspects of the product.
- **Language understanding:** Should be well-versed in one of the languages printed on the product package.
- **Knowledge:** Should be well-versed in infusion therapy delivery systems.

MATERIAL OF CONSTRUCTION:
PP, ABS, PVC, Nylon, Latex/Isoprene, PC, PTFE, HDPE, Stainless Steel, Silicone.

MEDICAL/CLINICAL CONDITIONS:
Infusion Set helps healthcare professionals to reliably administer IV fluids, electrolytes and nutrients directly from the container into a patient's vascular system through the IV Catheter/hypodermic needle inserted into the patient's vein. The intravenous route of administration is commonly used for rehydration or to provide nutrients for those who cannot, or will not (—due to reduced mental states or otherwise) — consume food or water by mouth and for treatment of various conditions such as dehydration, electrolyte imbalance, etc. It may also be used to administer other medical therapy such as electrolytes to correct electrolyte imbalances.

INDICATIONS FOR USE:
Infusion Sets are indicated for delivery of fluids intravenously to patient's requiring treatment for various conditions such as dehydration, electrolyte imbalance.
Intravenous Administration Set is a collection of Piercing Spike, Drip Chamber, Tubing, Flow controller Body, Roller & Rubber bulb/Luer Lock intended to conduct fluids from an intravenous (IV) administration bag/bottle to a peripheral venous cannula (not included) where gravity provides the force to transport the fluid into a patient's venous system.
Infusion Set is Gravity Feed, Sterile, Non-pyrogenic, Single-use, disposable device**.**

MODE OF ACTION:
Intravenous (IV) administration **avoids the first-pass metabolism effect resulting in direct entry of electrolyte/fluid into the systemic circulation which results in immediate effect**. Intravenously administered drugs are given either as a "bolus" (within 1–30 min) or an infusion over a period of many hours.

INTENDED PATENT POPULATION:

These infusion sets may be used for all age groups with consideration given to adequacy of vascular anatomy and appropriateness of the procedure.

DURATION OF USE:

Infusion Set shall not be used for a period more than 24 hours (if used along with hypodermic needle), and not more than the period of 72 hours (if used with any other peripheral vascular access device) if anyone uses a device beyond the intended duration of use, will bear the full responsibility for its safety and effectiveness.

CONTRAINDICATIONS:

- Infusion Set and its variants are not intended for delivery of:
  - blood or blood components, and
  - insulin & viscous fluids.
- Infusion Set and its variants are not intended to be used in patients:
  - With known hypersensitivity to any of the materials used in construction of device, and
  - Suffering from oedema.

IMPLICATIONS AND CONSEQUENCES DUE TO RE-USE OF SINGLE-USE DEVICE:

Infusion Set is designated as 'Single-use' hence, must not be re-used. It should only be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.

Re-use of Single-use Infusion Set could lead to several safety Issues:

- Re-use or reprocessing single-use devices may compromise their intended function.
- Re-use or Reprocessing a single-use device may alter its characteristics so that it no longer complies with the original manufacturer's specifications and, therefore, the performance may be compromised.
- Re-use or Reprocessing a single-use device could lead to cross-infections.

GENERAL WARNINGS & PRECAUTIONS:

- Carefully inspect the packaging of product and use the product only if:
  - Sealing is found intact, and
  - Components of product are intact.
- Return the product to us if packaging is damaged, deformed or components are detached or missing.
- Use latex-free variant of product if patient is known to allergic from latex.
- If hypodermic needle is used for vein-penetration purpose, then device shall be used only for 24 hours. The needle and the device then shall be discarded in accordance with applicable local or national regulatory framework for medical device disposal.
- Do not attempt to re-sterilize this device. Re-sterilization on this product has not been validated. Re-sterilization of the device will have a detrimental effect on its known properties thereby rendering it inappropriate for the use.
- Single-use product is guaranteed Non-toxic, Sterile & Non- pyrogenic if the packaging of the product is not damaged or deformed.

- Do not use the product beyond the intended duration of use as prescribed by manufacturer. i.e. 24Hrs (with hypodermic needle) and 72 hours (if use along with any other peripheral vascular access device).
- Discard or dispose the Single-use infusion Set, in accordance with accepted medical practice and applicable local, state and country laws and regulations after the use.

INSTRUCTIONS FOR USE OF INFUSION SET

PREPARATION FOR DECONTAMINATION:

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

SYSTEM PREPARATION:

- Check the unit package of the infusion set for any damage and see whether all the components of device are available. Do not use the product if the package is damaged or if any components (Protector Cap & Male Conical Fitting) are missing or loose.
- Check the label for manufacturing and expiry dates (do not use the medical device after expiry)

INSTRUCTIONS FOR USE:

- Take the infusion set out of the pouch and close the roller clamp.
- Take off the spike cap (Spike Protector Cap), and insert the spike into the rubber (up to its full length) connecting parts of the infusion bottle or infusion bag.
- Hang the infusion bottle or infusion bag inversely (upside down) and open the spike's air-vent cap (if available).
- Open the roller clamp and allow the fluid to enter the drip chamber (if required squeeze the drip chamber) until the fluid occupies 1/2-2/3 of the drip chamber and then close the roller clamp.
- Open the roller clamp, drain off the entrapped and again close the roller clamp.
- Connect the distal end of infusion set with 6% female conical fitting and use the device for infusion.
- Connect to intended devices for infusion & adjust the desired flow rate by use of flow regulator (manually rotate the roller to adjust the flow).
- Do not overtighten if resistance is felt or interaction between components is failing.
- Designed to deliver 20 or 60 drops of distilled water equivalent to 1 ± 0.1ml (1 ± 0.1g)

DEVICE DISPOSAL SYSTEM:

Discard the infusion set 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.

STORAGE CONDITION:

This product shall be stored in a clean and dry environment with good ventilation facility.

Recommended Storage Temperature : 10^0C to 40^0C

Relative Humidity : 60 ± 5%

POTENTIAL COMPLICATIONS:

- Local infections
- Venous thrombophlebitis

- Extravasation of infused fluids into surrounding tissues
- Hypervolaemia
- Air embolism
- Infiltration

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.

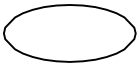
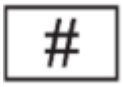
PACKAGING:
The device is supplied in a soft blister pack/ribbon pouch/paper pouch, along with IFU, inner labels in a duplex box and with external identification labels.

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
	Liquid filter with pore size		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		Drops per milliter
	Gravity Feed Only		

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