ANNEXURE-XIII
INSTRUCTION FOR USE
(TLF/LML/003)

1.0 INSTRUCTION FOR USE

1.1 PRODUCT FAMILY: Sterile Hypodermic Needle for Single Use. (16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G & 30G).

1.2 BASIC UDI: 890615878LML003LY

1.3 MATERIAL USED: Polypropylene, Adhesive (Glue) and Stainless Steel 304.

1.4 DEVICE DESCRIPTION: Sterile hypodermic needle shall be consisting of a SS capillary tube that is sharpened at one end and at the other end joined with a female connector called hub, designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set.

1.5 INTENDED USE: The sterile hypodermic needle is intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose**.**

1.6 INDICATIONS FOR USE: A hypodermic needle is used for rapid delivery of liquids, or when the injected substance cannot be ingested.

1.7 INTENDED USER: Sterile hypodermic single use needle used for all individuals (newborn to adults to old age), for administrations of injections or medicinal fluids. The medical device shall be used by qualified trained medical staff.

1.8 PATIENT POPULATION: Sterile hypodermic single use needle can be used for all individuals (newborn to adults to old age), needs administrations of injections or medicinal fluids. The medical device shall be used by qualified and specifically trained medical staff.

The selection of hypodermic needle for usage on patients is dependent on combination of patient age, physical condition and medication requirements.

1.9 CONTRAINDICATIONS:

1.9.1 Device must not be used other than as indicated in intended use.

1.9.2 Device should not be used for administration of blood and blood components.

1.9.3 Device should not be used for large volume fluids and fluids derivatives.

1.9.4 Device should not be used for administration of high viscous fluids.

1.9.5 Device should not be used on patients with known hypersensitive to device material.

1.10 ⚠ CAUTION:

1.10.1 Device is single use only.

1.10.2 Device must not be reused. Reuse of the device may cause serious infection, cross contamination, transmission of bacteria, viruses and blood related transfusion of serious diseases.

1.10.3 Ensure before use that device/packing is not tempered or damage.

1.10.4 Device for manual use only.

1.11 DISCLAIMER:

1.11.1 The Medical device is supplied with limited functionality, Lifelong Meditech does not warrant any foreseeable risk resulting from improper/ misuse of the medical device.

1.11.2 Device should not be used out of its indications/instructions for use. In-case the device is used out of its instructions described, the manufacturer/supplier must be informed for any usage outside of its recommendations.

1.12 INSTRUCTION FOR USE:

1.12.1 Inspect package for integrity and expiry and then remove the needle from package.

1.12.2 Be careful to pull the needle cap straight off to avoid the needle point damage.

1.12.3 Push and twist the needle clock wise on the syringe tip to seal it firmly and ensure a tight fitting.

1.12.4 Take or withdraw the medicinal fluids.

1.12.5 Expel, air bubble through open end before injection.

1.12.6 Device is single use only. Do not re-sterile. Device should be discarded after one procedure. It's extremely difficult to clean exactly after being expressed to biological materials and may causes adverse patient reactions if reuse, the cleaning of these devices may alter their structural property accordingly. Lifelong Meditech will not be responsible for direct incidental and consecution damages resulting for reuse.

1.13 STORAGE OF THE DEVICE: - Store in cool and dry place. Note: Avoid exposure to direct sunlight.

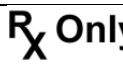
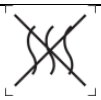
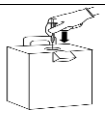
1.14 SELF LIFE OF THE DEVICE: 05 Years from the manufacturing date.

1.15 DISPOSAL METHOD: Used medical device is considered as biohazard waste. Dispose-off the used medical device in accordance with hospital, administrative and/or local government policy.

1.16 ADVERSE EVENT: The device is supplied with limited functionality, and there is no foreseeable risk associated with the device usage. Consequences from the improper use may cause or lead to redness, swelling, bruising etc.

1.17 For any feedback or query, customer/user can write or reach to us at:
Email- lmlcustomercare@lifelongindia.com **or** Customer Care No: +91-124-4406600

1.18 LABEL INFORMATIONS:

Symbol	Description
	Device to be sale on order/prescription of a Physician/ Doctor/ Paramedical staff only
	Catalogue number
	Lot number: Batch number
	Expiry date: Device can be used until the end of the month indicated
	Sterilization with ethylene oxide gas
	Single use only
	Manufacturer
	Caution
	Conformité Européenne (**CE marking** is a mandatory conformity marking for certain devices sold within the European Economic Area)
	Do not re-sterilize
	Non-pyrogenic
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Authorized representative in the European community
	Consult instruction for use
	Safe disposal of medical device

ANNEXURE-XIII
INSTRUCTION FOR USE
(TLF/LML/003)

Symbol	Description
	Do not use hook
	Store and stack in upright condition
	Fragile, handle with care
	Unique device identifier
	Single sterile barrier system (For primary package only)
	Medical device
	Country of Manufacture

Lifelong Meditech Private Limited,
Plot No. 18, Sector – 5, IMT Manesar,
Gurgaon – 122050, Haryana (INDIA),
Mfg. License No. MFG/MD/2019/000203
lmlcustomercare@lifelongindia.com
Customer Care No: +91-124-4406600

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