

**ANNEXURE-XIII
INSTRUCTION FOR USE
(TLF/LML/007)**

1.0 INSTRUCTION FOR USE

- 1.1 PRODUCT FAMILY: Non-sterile hypodermic single use syringe without needles (Bulk Pack)**
(1mL 2mL, 2.5mL, 3mL, 5mL, 10mL, 20mL, 30mL, 50mL & 60mL).
- 1.2 BASIC UDI:** 890615878LML007M8.
- 1.3 MATERIAL USED:** Polypropylene and Thermoplastic Elastomer or Isoprene (IR).
- 1.4 DEVICE DESCRIPTION:** A syringe is simply consisting of a plunger/piston & gasket that's fits tightly within a cylindrical tube called a barrel. The plunger can be linearly pulled and pushed along the inside of the barrel, allowing the syringe to take-in and expel liquid or gas through a discharge barrel tip at the front (open) end of the barrel.
- 1.5 INTENDED USE:** The Product is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.
- 1.6 INDICATION FOR USE:** Hypodermic syringe with needle is intended to be used for medical purpose to inject fluids into or withdraw fluids from the body.
- 1.7 INTENDED USER:** Syringe with hypodermic needle can use for all individuals (newborn to adults to old age), needs administrations of injections or medicinal fluids. The medical device shall be used by qualified, trained medical staff.
- 1.8 PATIENT POPULATION:** Hypodermic syringe with 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, trained medical staff.

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

1.9 ACCURACY:

| Tolerance of Nominal capacity | | |
|--------------------------------------|-----------------------------|--------------------------------|
| S. No | Nominal capacity of syringe | Tolerance for nominal capacity |
| 1 | 1mL | ± 5% |
| 2 | 2mL | ± 5% |
| 3 | 2.5mL | ± 5% |
| 4 | 3mL | ± 5% |
| 5 | 5mL | ± 4% |
| 6 | 10mL | ± 4% |
| 7 | 20mL | ± 4% |
| 8 | 30mL | ± 4% |
| 9 | 50mL | ± 4% |
| 10 | 60mL | ± 4% |

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1.10 CONTRAINDICATIONS:

- 1.10.1 Device must not be used other than as indicated in intended use.
- 1.10.2 Device should not be used for administration of blood and blood components.
- 1.10.3 Device should not be used for large volume fluids and fluids derivatives.
- 1.10.4 Device should not be used for administration of high viscous fluids.
- 1.10.5 Device should not be used on patients with known hypersensitive to device material.

1.11 INSTRUCTION FOR USE:

- 1.11.1 Ensure the syringe should be sterilized before use. Inspect package for expiry and then remove the syringe from package.
- 1.11.2 Attached the syringe with a hypodermic needle.
- 1.11.3 Be careful to pull the needle cap straight off to avoid the needle point damage.
- 1.11.4 Push and twist the needle clock wise on the syringe tip to seal it firmly and ensure a tight fitting.
- 1.11.5 Take or withdraw the medicinal fluids.
- 1.11.6 Expel, air bubble through open end before injection.
- 1.11.7 Device is single use only. Do not re-sterile. Syringe 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.

1.12  CAUTION:

- 1.12.1 Please ensure that non-sterile hypodermic syringes must be sterilized before use.
- 1.12.2 Device is single use only.
- 1.12.3 Device must not be reused. Re-use of the device, may cause serious infection, cross contamination, transmission of bacteria, viruses and blood related transfusion of serious diseases.
- 1.12.4 Ensure before use that device/packing is not tempered or damage.
- 1.12.5 Device for manual use only.

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1.13 DISCLAIMER:

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

1.13.2 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.

1.14 STORAGE OF THE DEVICE: Store in a clean, dry and ventilated area at 0°C to 30°C. Avoid direct sunlight and extreme heat sources.

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












1.16 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.

1.17 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.

1.18 For any feedback or query, customer/user can write or reach to us at:

Email- lmcustomercare@lifelongindia.com **or** Customer Care No: +91-124-2330124

1.19 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 |
|  | Non-Sterile |
|  | 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 |

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| Symbol | Description |
|--------|--------------------------------------|
| | Do Not Use if Package is Damaged |
| | Keep Dry |
| | Keep Away From Sunlight |
| | Date of Manufacturing |
| | Authorized Representative |
| | Consult Instruction For Use |
| | Safe Disposal of syringe |
| | Do Not use hook |
| | Store and stack in upright condition |
| | Fragile, handle with care |
| | Unique device identifier |
| | Medical device |
| | Country of Manufacture |

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