

**ANNEXURE-XIII
INSTRUCTION FOR USE
(TLF/LML/008)**

1.0 INSTRUCTION FOR USE

- 1.1 PRODUCTS FAMILY:** - Sterile single-use syringes with or without needle for Insulin (U-40 & U-100).
- 1.2 BASIC UDI:** 890615878LML008MA
- 1.3 MATERIAL USED:** - Polypropylene, Thermoplastic Elastomer, SS 304.
- 1.4 DEVICE DESCRIPTION:** Syringes for insulin is a plastic syringe designed for subcutaneous injection of a desired dose of insulin. The Insulin syringe consists of a graduated barrel, plunger rod and needle/hub assembly. The Insulin syringes are sterile, single use, and non-pyrogenic. This device operates as on similar principles of piston syringes.
- 1.5 INTENDED USE:** - Product is intended to subcutaneous inject the desired dose of insulin.
- 1.6 INDICATIONS FOR USE:** - The insulin syringe is used for delivery of insulin, or when the injected substance cannot be ingested.
- 1.7 INTENDED USER:** - Device should be used by a Doctor/Registered Practitioner or Paramedic staff or a patient, as guided by healthcare professional.
- 1.8 PATIENT POPULATION:** The single uses Syringes for insulin are designed for administration of insulin to all individuals (newborn to adults to old age). The insulin syringe may be used by a patient or by a healthcare professional, either in the home setting, in a hospital, or a clinical setting.
- 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 INSTRUCTION FOR USE:**
 - 1.10.1** Inspect package for integrity and expiry and then remove the Insulin syringe from package.
 - 1.10.2** To expose needle, twist protective cap to break seal, then pull straight off, being careful not to bend needle and to avoid needle point damage.

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- 1.10.3** To measure correct dose, align top edge of the plunger with your dosage on the insulin syringe scale.
- 1.10.4** To prevent misuse after injection, destroy syringe needle and put in a container for safe disposal.
- 1.10.5** Device is single use only. Do not re-sterile. Insulin 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 devices may alter their structural property accordingly. Lifelong Meditech will not be responsible for direct incidental and consecution damages resulting for reuse.
- 1.10.6** Follow below mentioned steps for using the insulin syringes:

Step-1: Open package by peeling back paper and remove syringe carefully.



Step-2: Remove protective needle sheath/ cap carefully to avoid needle point damage.



Step-3: Draw up medication and administer injection using an aseptic technique in accordance with your facility's protocol.

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Step -4: Once the insulin syringe used, immediately dispose of syringe in an approved sharps disposal Container.



1.11  **CAUTION:**

1.11.1 Device is single use only.

1.11.2 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.

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

1.11.4 Device for manual use only.

1.12 DISCLAIMER:

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

1.12.2 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.

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

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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.




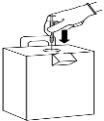







1.16 ADVERSE EVENT: The device is supplied with limited functionality, and there is no foreseeable risk associated with the device usage. Consequences from the improper use may cause or lead to redness, swelling, bruising etc.


1.17 For any feedback or query, customer/user can write or reach to us at:
Email- lmcustomercare@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 (Manufactured By)
	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

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Symbol	Description
	Date of Manufacturing
	Consult Instruction For Use
	Authorized Representative
	Safe Disposal of syringe
	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

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