

1.0 INSTRUCTION FOR USE

- 1.1 **PRODUCT FAMILY: Sterile Hypodermic single use Syringe with/without Needles** (1mL, 2mL, 2.5mL 3mL, 5mL, 10mL, 20mL, 30mL and 50mL) with needle sizes (16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G & 30G).
- 1.2 **BASIC UDI:** 890615878LML001LU.
- 1.3 **MATERIAL USED:** - Polypropylene, Thermoplastic Elastomer, Stainless Steel (304).
- 1.4 **DEVICE DESCRIPTION:** A syringe is a 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 tube/barrel, allowing the syringe to take-in and expel liquid or gas through a discharge orifice/nozzle/barrel tip at the front (open) end of the tube/barrel. The open end of the syringe may be fitted with a hypodermic needle, a nozzle or tubing to help direct the flow into and out 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:** - Sterile hypodermic single use syringe with needle or without needle to be used for medical purpose to inject fluids into or withdraw fluids from the body.
- 1.7 **INTENDED USER:** Sterile hypodermic single use syringe can be 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 syringe 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 Syringe & 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 **INSTRUCTION FOR USE:-**
 - 1.10.1 Inspect package for integrity and expiry and then remove the syringe from package.
 - 1.10.2 Be careful to pull the needle cap straight off to avoid the needle point damage.

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- 1.10.3 Push and twist the needle clock wise on the syringe tip to seal it firmly and ensure a tight fitting.
- 1.10.4 Take or withdraw the medicinal fluids.
- 1.10.5 Expel, air bubble through open end before injection.
- 1.10.6 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.
- 1.11  **WARNINGS/PRECAUTIONS: -**
- 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.
- 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- lmlcustomer@lifelongindia.com **or** Customer Care No: +91-124-4406600

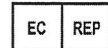
1.18 LABEL INFORMATION: -

Symbol	Description
R_x Only	Device to be sale on order/prescription of a Physician/ Doctor/ Paramedical staff only
REF	Catalogue Number
LOT	Lot Number: Batch Number
	Expiry date: Device can be used until the end of the month indicated
STERILE EO	Sterilization with ethylene oxide gas
	Single use only
	Manufacturer
	Warnings
CE 2460	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 manufacturing
EC REP	Authorized Representative
	Consult Instruction for Use
	Safe disposal of syringe
	Do not use hook

**ANNEXURE-XIII
INSTRUCTION FOR USE
(TLF/LML/001)**

Symbol	Description
	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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