
1.0 INSTRUCTION FOR USE

1.1 PRODUCT FAMILY: Sterile Hypodermic Safety Needles for Single Use (16G, 18G, 19G ,20G, 21G, 22G, 23G, 24G, 25G and 26G)

1.2 MATERIAL USED: - Polypropylene, SS304.

1.3 DEVICE DESCRIPTION: Sterile hypodermic safety needle shall be consists 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.

Hypodermic safety needle is commonly used with a syringe, a hand-operated device with a plunger, to inject substances into the body (e.g., saline solution, solutions containing various drugs or liquid medicines) or extract fluids from the body (e.g., blood). They are used to take liquid samples from the body, for example taking blood from a vein in venipuncture.

After administration/injecting of the drugs (contents) through safety needle, the Re-use prevention (RUP) feature (clip over the needle) to be activated manually, or as shown it's IFU, to prevent the happening of needle stick injury and re-use of device.

1.4 INTENDED USE: Sterile hypodermic safety needle is intended for use in the aspiration and injection of fluids for medical purposes.

The safety needle is compatible for use with standard Luer slip & Luer lock syringes. Additionally, after withdrawal of the needle from the body, the attached safety sheath can be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticking.

1.5 INTENDED USER: Sterile hypodermic single use safety 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 trained medical staff.

1.6 PATIENT POPULATION:

Sterile hypodermic single use safety 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 trained medical staff.

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

**ANNEXURE-XIII
INSTRUCTION FOR USE (SAFETY NEEDLE)
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1.7 CONTRAINDICATIONS:-

- 1.7.1 Device must not be used other than as indicated in intended use.
- 1.7.2 Device should not be used for administration of blood and blood components.
- 1.7.3 Device should not be used for large volume fluids and fluids derivatives.
- 1.7.4 Device should not be used for administration of high viscous fluids.
- 1.7.5 Device should not be used on patients with known hypersensitive to device material.

1.8  CAUTION:-

- 1.8.1 Device is single use only.
- 1.8.2 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.
- 1.8.3 Ensure before use that device/packing is not tempered or damage.
- 1.8.4 Device for manual use only.

1.9 DISCLAIMER:

- 1.9.1 The Medical device is supplied with limited functionality, Lifelong Meditech does not warrant any foreseeable risk resulting from improper/ misuse of the medical device.
- 1.9.2 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.

1.10 INSTRUCTION FOR USE:-

- 1.10.1 Inspect package for integrity and expiry and then remove the safety needle from package using aseptic technique.
- 1.10.2 Select proper size of safety needle for injection.
- 1.10.3 Carefully select and clean the venipuncture or muscle site.
- 1.10.4 Be careful to pull the needle cap straight off to avoid the needle point damage.
- 1.10.5 Device is single use only. Do not re-sterile. Safety needle 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.

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1.10.6 To Avoid the re-use and for precautionary purpose of safety needle, The Safety Needle should be use by following steps:-

STEP 1:- Tighten the syringe to the safety needle using aseptic technique, grip the base of the needle, not the safety sheath, push and turn the syringe clockwise.



STEP 2:- Move the safety sheath away from the needle and toward the syringe barrel to the angle shown, prior to removing the needle cap. Perform injection procedure according to established technique. (Note: The needle “bevel up” position is oriented to the position of the safety sheath.)



STEP 3:- After the injection procedure, use a one-handed technique to activate the safety mechanism using any of the three (3) methods illustrated above. (Activation is verified by an audible and/or tactile “click” and can be visually confirmed.)



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STEP 4:- Visually confirm that the safety sheath is fully engaged.



1.11 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.




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

1.13 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.

















1.14 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.


1.15 For any feedback or query, customer/user can write or reach to us at:
Email- lmlcustomercare@lifelongindia.com or Customer Care No: +91-124-2330124

1.16 LABEL INFORMATIONS:-

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

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	Caution
	Do Not Re-sterilize
	Non Pyrogenic
	Do not use if package is damaged
	Keep Dry
	Keep Away From Sunlight
	Date of manufacturing
	Consult Instruction for Use
	Safe Disposal
	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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