

Safety Needle

Safety Needle & How to Use Guide

The instructions are applicable for all Safety Needle models

DESCRIPTION:

The Safety Needle features a robust shield that encases the entire needle after activation. Its proprietary integrated locking mechanism prevents deactivation of the device once the safety shield has been locked into place and can be activated by using a thumb, finger, or a flat surface. It is commonly used with luer or luer lock connection devices.

INTENDED USE

The primary function of the device is to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The needle stick prevention feature of the device helps prevent accidental needle sticks by shielding the needle after use.

INTENDED USERS:

Trained Medical Professional and/or Trained Healthcare Provider

PRECAUTIONS:

1. Carefully follow the instructions for use.
2. Product cannot be reused or re-sterilized.
3. Do not autoclave before use.
4. Keep hands away from needle tip at all times.
5. Do not attempt to override or defeat the safety locking mechanism.
6. Do not use if needle is bent or broken

TARGETED PATIENT POPULATION:

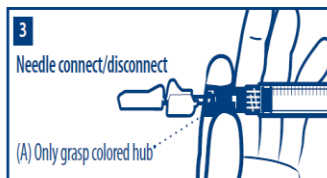
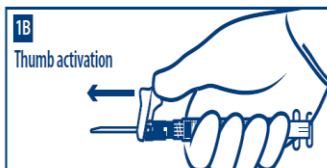
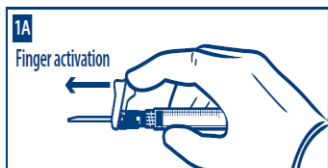
All patient populations as determined by the clinical professional.

PRODUCT DETERIORATION

The content of the unopened and undamaged units is guaranteed to be sterile. Sterile Safety Needle should not be used if (1) there is evidence of damage or contamination to the product, (2) the expiration date has passed, (3) the Safety Needle package is open or damaged, or (4) there are other signs of deterioration.

INSTRUCTIONS FOR USE:

NOTE: Sterile gloves and protective clothing and eye wear should be worn when handling Safety Needle.



1. To open package, peel back paper tabs completely exposing the Safety Needle. Use aseptic technique.
2. Attach Safety Needle to any luer lock or regular luer syringe. Twist syringe clockwise while holding the rigid sheath that covers the Safety Needle to seat the Safety Needle to the syringe.
3. Remove the sheath from the Safety Needle while directing the needle away from you and others. Be certain not to touch the needle or the needle safety shield.
4. If performing injection, draw medication into syringe and use aseptic technique.
5. If necessary to transport filled syringe to point of administration, use a safe, passive recapping technique to cover the needle before transport. In accordance with OSHA standards, such recapping must be accomplished by a one-handed technique, i.e., do not hold the needle shield during the recapping process.
6. Perform injection (or aspiration of body fluid) according to local standard procedure and aseptic technique.
7. Immediately following the injection or aspiration procedure, lock the safety needle shield using any of the following methods:
Push the safety shield forward in a single-handed manner to cover the needle and lock the shield. Keep your finger (Fig. 1A — Finger Activation) or thumb (Fig. 1B — Thumb Activation) behind the needle tip at all times or press the safety shield, lever side down, onto a flat surface to cover the needle and lock the shield, i.e., above table (Fig. 2 — Surface Activation).

Safety Needle

8. The Safety Needle is locked once the needle tip is completely shielded. Verify locked position through audible, tactile, and/or visual feedback.

9. Only grasp the coloured hub to connect/disconnect needle from syringe (see Fig. 3 — Locked Needle Shield). (A) = Coloured Hub. (Only Grasp Coloured Hub.)

10. Once safety shield is locked, immediately discard the Safety Needle and syringe into the nearest sharps container following applicable regulations.

WARNINGS

1. These devices are intended for single use only. Do not re-sterilize and/or reuse as this can potentially result in a compromised device performance and the increased risk of inappropriate sterilization and cross contamination. 2. Do not re-pack. 3. Not suitable for any other application than intended use. 4. Device should be disposed of in accordance with the facility protocol. Failure to follow instructions may result in a failure of the device. 5. The use of this product, in association with a kit should be previously validated by the user/ kit manufacturer. 6. Do not use if the needle is visibly damaged. 7. Directions for use must be followed carefully. The manufacturer cannot be held responsible for any unauthorized or unqualified use of the product. 8. To be handled by HealthCare professional/physicians. 9. Contaminated needles should not be re-capped or the safety shield removed.

WASTE DISPOSAL

Unused Safety Needle may be considered as non-hazardous waste and disposed of accordingly. Dispose of used needle as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products. It is the responsibility of the healthcare professional to handle waste produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with applicable regulations.

CUSTOMER SERVICE

For product technical support or in case of complaints please contact SteriPack Medical Poland at www.steripackgroup.com/incident-complaint/ or call at: +48 516-15-739 / +48 515-181-891


LIMITED WARRANTY

Unused needles must be stored according normal storage conditions and they can be used only up to the expiry date printed on the packaging/blister. For the applicable warranty period, SteriPack warrants that each product shall be (i) of good quality and free of material defects, (ii) function in accordance with the material specifications referenced in the product insert, and (iii) approved by the proper governmental agencies required for the sale of products for their intended use (the "limited warranty").

ADVERSE REACTIONS:

- Pain, redness, swelling of injection site
- Bruising or irritation of skin
- Infection

MANUFACTURER INFORMATION

 SteriPack Medical Poland Sp. z o. o.
registered also under S.M.P. Sp. z o. o.
Leg, ul. Japońska 1
Jelcz-Laskowice, PL 55-220



Manufacturer



Sterilized using Irradiation



Single sterile barrier system



Notified Body Number



Do not re-use



Caution



Non-pyrogenic



Medical Device



Don't use if package is damaged



Prescription-only



Global Trade Item Number



Batch code



Use by



Catalogue number



Manufacturing date