

## INSTRUCTION FOR USE

### Safety Needle

#### MANUFACTURER

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

#### TECHNICAL NOTES

Safety Needle is an easy to use, practical, and intuitive safety device with a robust shield that can be activated one-handed via multiple methods (finger, thumb or flat surface) for clinical flexibility. The safety shield is an integral part of the needle hub, and provides an audible and tactile click to confirm safety activation. It is a single-use device used with other luer connection devices and should be discarded in an approved sharps container.

#### 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 USER and USE ENVIRONMENT

Trained Medical Professional and/or Trained Healthcare Provider.  
Safety needle can be use in healthcare organizations, always with assurance a hygienic condition.

#### TARGETED PATIENT POPULATION

All patient populations as determined by the healthcare professional.

#### CONTRAINDICATIONS

None identified

#### TEST PRINCIPLES

The safety needle can be used to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin always after healthcare professional use decision.  
Safety needles are not dedicated to self-use.

#### WARNINGS

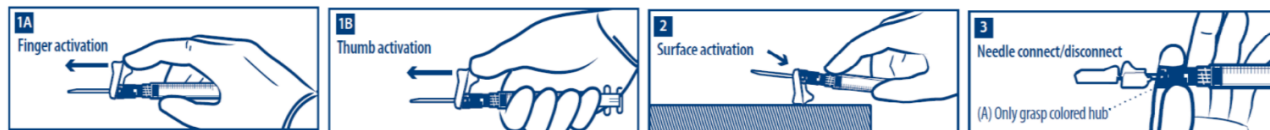
**1.** Do not autoclave before use. Keep hands behind the safety shield at all times. Do not attempt to override, remove, or defeat the safety locking mechanism. Do not use if needle is bent or broken. **2.** Device should be disposed of in accordance with the facility protocol. Failure to follow instructions may result in injury or a failure of the device. **3.** Failure to properly connect the needle to the device may result in air or fluid leaks. **4.** Recapping may increase the risk for user injury. Although recapping is not recommended, please do so in accordance with your facility policy and protocols. **5.** Failure to follow instructions may result in a failure of the device. **6.** Directions for use must be followed carefully and handled by Healthcare Professional. **7.** The manufacturer cannot be held responsible for any improper or inadequate techniques of device application.

#### PRECAUTIONS

**1.** Do not autoclave before use. **2.** Keep hands behind the safety shield at all times. **3.** Do not attempt to override, remove, or defeat the safety locking mechanism. **4.** Do not use if needle is bent or broken. **5.** Do not use if device or package is damaged or contaminated. **6.** Do not use beyond the expiration date printed on the sealed pouch. Do not re-pack. **7.** Not suitable for any other application than intended use.

**INSTRUCTION FOR USE**

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



- # Steps**
1. Identify the type of needle, gauge, and length using the International Organization for Standards (ISO) color coded standard that best fits the need of the procedure.
  2. To open package, peel back film tabs halfway, starting from "peel", exposing the Safety Needle. Use aseptic technique.
  3. Attach Safety Needle to any luer connection device (e.g. syringe). Twist clockwise while holding the rigid sheath to seat the needle to the device.
  4. 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.
  5. If re-capping prior to use, do so in accordance with OSHA guidelines or your facility's protocol.
  6. Perform procedure according to your facility's protocol.
  7. Immediately following use, engage the safety mechanism 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 safety shield 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).
  8. The Safety Needle is locked once the safety shield is fully extended, completely covering the needle, an audible tactile click is heard.
  7. Only grasp the colored hub to connect/disconnect needle from device, see Fig. 3 (A) = Colored Hub.
  8. Once safety shield is locked, immediately discard the Safety Needle into the nearest sharps container following applicable regulations.

**CAUTION**

None identified

**RESIDUAL RISKS/UNDERSIABLE SIDE-EFFECTS**

None identified

**CUSTOMER SERVICE**

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

For product complaints or medical incidents please complete questionnaire at:

[www.steripackgroup.com/incident-complaint](http://www.steripackgroup.com/incident-complaint).

Please note, needle that have been used will not be accepted for returns.

**MANUFACTURER INFORMATION AND USED PICTOGRAMS**

	Manufacturer		Batch number		Medical Device
	Sterilized using irradiation		Manufacturing date		Single sterile barrier system
	Catalogue number		Use-by date		Caution
	Read e-instruction for use at: <a href="http://steripackgroup.com/ifu/">steripackgroup.com/ifu/</a>		Unique Device Identifier		Do not re-use
	Prescription only		CE mark with Notified Body number		Do not use if package is damaged
	Package may be disposed together with nylon, acrylic glass, ABS, polycarbonates.		Contains hazardous substance		Do not re-sterilize