

REF	Description	Hub Color
27704	21G X 3/4" 12" TUBE	Green
27706	23G X 3/4" 12" TUBE	Deep Blue
27708	25G X 3/4" 12" TUBE	Orange

Instructions For Use (IFU)

Table of Contents

- 1 Device Description
- 2 Intended Use
- 3 Indications for Use/Target Users
- 4 Benefits of Use
- 5 Warnings / Precautions
- 6 Contraindications
- 7 Sterility
- 8 Operating Instructions
- 9 Storage

1 Device Description

1.1 The Securetouch Safety Scalp Vein Set is a single-use device which consists of a stainless steel hypodermic needle, needle cap, wing, wing protector with stopper (safety mechanism) and tubing

2 Intended Use

2.1 The Safety Scalp Vein Set is intended to be used with disposable syringe or disposable infusion/transfusion set for medicine infusion and blood collection.

3 Indications for Use/Target Users

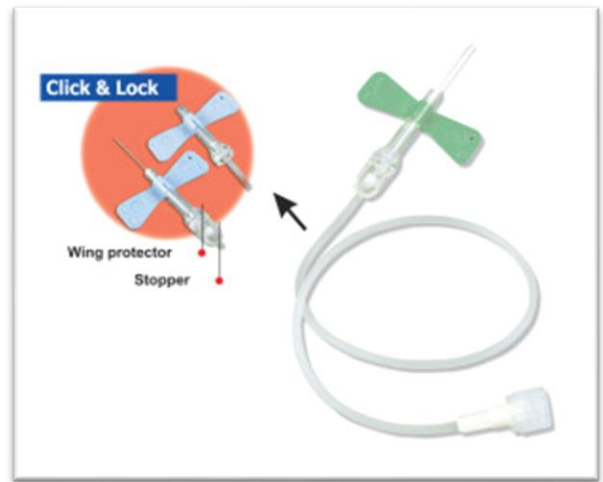
- 3.1 The Safety Scalp Vein Set is indicated for general patient use in a clinical setting.
- 3.2 The device is designed for use by a qualified physician or clinician.
- 3.3 The device is intended for use with the general patient population.

4 Benefits of Use

- 4.1 Safe, easy to use.
- 4.2 Thin wall stainless steel cannula is siliconized for easy insertion.
- 4.3 Color-coded for easier identification.
- 4.4 Flexible wings hold the needle in position and help to prevent inadvertent pull out.

5 Warnings/Precautions

- 5.1 For single use only.
- 5.2 Discard after use.
- 5.3 Do not reuse. Reuse of needle can result in



- contamination or transmit disease.
- 5.4 Please refrain from carelessly releasing the lock, forcefully pulling the wing or such actions, since rough handling of the device may damage it.
- 5.5 Due to the risk of coming into contact with blood, please wear gloves and eye protector as per CDC guidelines.
- 5.6 Do not release forcefully or destroy the accidental needlestick prevention mechanism after it has been activated.
- 5.7 The tubing on this device does not contain NON-(2-ethylhexyl) phthalate.
- 5.8 When immobilizing the wing, be careful not to apply tape to the stopper section, since taping the stopper prevents activating the safety mechanism. See Figure 5.
- 5.9 Due to the risk of blood dripping from its exposed tip, promptly dispose of the product pointing to the needle tip upward in an approved disposal container after activating the safety mechanism and closing the clamp securely.
- 5.10 When the secure mechanism is being activated, keep hands away from the needle tip at all times.
- 5.11 There is the possibility of blood, solution, etc. leaking out of the product when removing the luer connector. Be careful.
- 5.12 While using and during post-use disposal, pay close attention to prevent accidental needlestick.

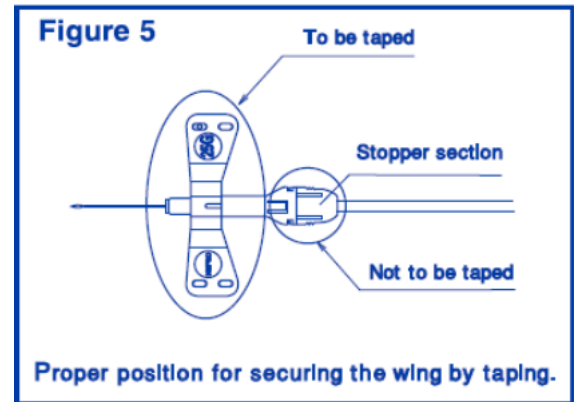


Figure 5. Proper position for securing the wing by taping.

6 Contraindications

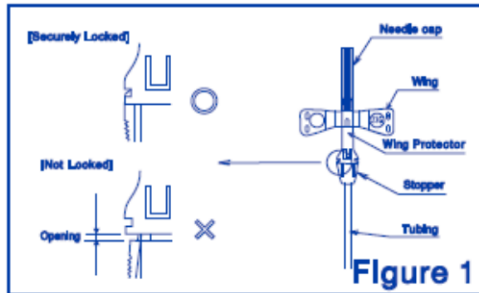
- 6.1 There are no recognized contraindications for the use of Safety Scalp Vein Sets.

7 Sterility

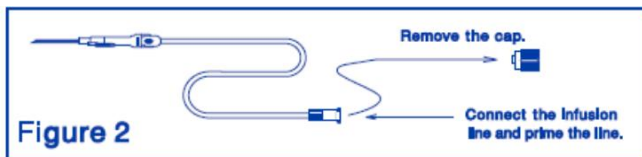
- 7.1 Safety Scalp Vein Sets are sterilized by EO gas sterilization (indicated by single use only.
- 7.2 Do not re-use .
- 7.3 Do not re-sterilize.
- 7.4 Inspect each package prior to use.
- 7.5 Do not use the device if any seal or cavity is damaged or breached or if the expiration date has been exceeded. Once opened, the device must be used or discarded.

8 Operating Instructions

- 8.1 Remove the Safety Scalp Vein Set from its packaging.
- 8.2 Check to make sure that the wing protector is securely locked into the stopper. See Figure 1.



- 8.3 Connect the Safety Scalp Vein Set to an appropriate device. Remove the connector cap from the luer connector to the infusion line and then prime the line. See figure 2.
- 8.4 Check to make sure that the female luer is securely attached to the male luer of the connecting device.



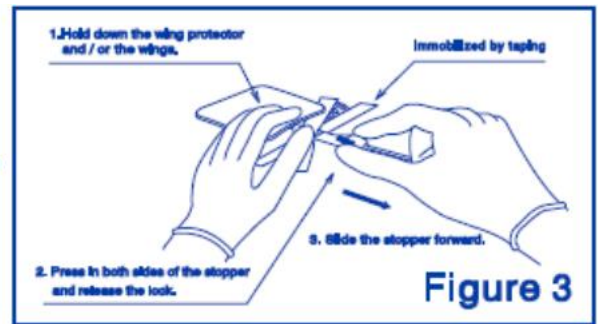
- 8.5 Prepare the venipuncture site with the appropriate antiseptic.
- 8.6 Remove needle cap by grasping the wing. Be cautious with the exposed needle tip.
- 8.7 Insert the needle into the disinfected puncture area.
- 8.8 Make sure that the needle tip is securely in the blood vessel by confirming blood flashback visibly in the wing protector and then immobilize the wing by tape.
- 8.9 Adjust the infusion set clamp, make sure that the solution is flowing, then begin the infusion.

Activation of Safety Mechanism

The following procedures are used to active the accidental needlestick prevention mechanism. It is recommended to use a pre-removal activation, but a post-removal activation can also be applicable.

Pre-Removal Activation

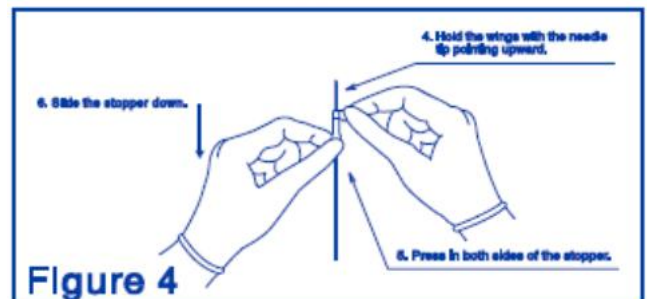
- 8.10 After the completion of the infusion, close the clamp on the infusion line, and apply digital pressure to the puncture area using a sterilized gauze pad, and using the same hand, hold down the wing protector and/or the wings. See figure 3.
- 8.11 With the other hand, release the lock by pressing in both sides of the stopper. See Figure 3.
- 8.12 NOTE: Do not apply undue pressure to the puncture site, slide stopper forward until it becomes completely fixed with an audible or tactile click. See Figure 3.
- 8.13 Verify that the stopper is securely immobilized against the wing protector. Thus, the needle is completely retracted and protected in the wing protector.



- 8.14 Maintain pressure on the puncture site according to the facility protocol.
- 8.15 Remove tape from the Safety Scalp Vein Set and promptly dispose of the used set in accordance with regulatory guidelines set by OSHA, CDC and the facility.

Post-Removal Activation

- 8.16 After the completion of the infusion, close the clamp on the infusion line, and remove the tape from the set and apply digital pressure to the puncture area using sterilized gauze pad, and grasp the Wing Protector (not the stopper) with the other hand.
- 8.17 Remove the needle while using sufficient care to prevent an accidental needle stick.
- 8.18 Maintain pressure on the puncture site according to the facility protocol.
- 8.19 After removing the needle, use one hand to hold the wings with the needle tip pointing upward. Be careful of the needle tip. See Figure 4.
- 8.20 With the other hand, press in both sides of the stopper to release the lock. See Figure 4.
- 8.21 Slide the stopper down until it locks completely with an audible or tactile click. See Figure 4.
- 8.22 Verify that the stopper is securely immobilized against the wing protector.
- 8.23 Promptly dispose of the used set in accordance with regulatory guidelines set by OSHA, CDC and the facility.



9 Storage

- 9.1 Store at room temperature 15°C-25°C.
- 9.2 Do not store in high temperatures and humidity.
- 9.3 Keep away from direct sunlight.
- 9.4 Keep dry.
- 9.5 Store in a cool and dry place.

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	<p>EXELINT International, Co. 2500 Santa Fe Avenue, Redondo Beach, CA 90278 U.S.A. Tel: (310) 649-0707 Fax: (310) 649-1178 e-mail: info@med.com</p> <p>FOR U.S.A. INFO CALL: 800-940-3935 www.Exelint.com e-mail: info@Exelint.com</p>
 CE 2460	<p>EMERGO EUROPE Westervoortsedijk 60 6827 AT, Arnhem The Netherlands</p>

Graphic Symbol Legend for Medical Device Labeling

	Medical Device
	Catalog number
	Federal law (USA) restricts this device to sale by or on the order of a physician.
	Consult instructions for use
	Important Cautionary Information
	Sterilized by Ethylene Oxide. Sterility guaranteed if package unopened and undamaged.
	Manufacturer's Lot Number
	Unique Device Identifier
	Use by
	Date of Manufacture
	For single-patient-use only. Do not reuse.
	Do not use if package is damaged
	Keep away from sunlight
	Keep Dry
	Temperature Limit
	Non-Pyrogenic
	Single Sterile Barrier
	This device is not manufactured with Natural Rubber Latex
	Manufacturer
	Product marketed in European countries
	European Representative