

Saf-T Holder®

Technical Summary Sheet



DEVICE DESCRIPTION

The Jelco® Saf-T Holder® device is a sterile, multi-sample Luer adapter for venous blood sampling. The device may include a fixed back-end needle, vacuum tube holder, male or female Luer threaded connector, or culture bottle holder.

This product is compliant with OSHA directives as a result of permanent attachment of back-end needle and multi-sample Luer. The Jelco® Saf-T Holder® device provides safe and easy needle-less transfer following syringe draw and is available separately or with the Saf-T Wing® blood collection sets.

This product is provided sterile and non-pyrogenic. The materials used to manufacture this blood culture device do not contain latex and are BPA.

This is an Rx device.

INDICATIONS*

The Saf-T Holder® device and Saf-T Holder® blood culture device are intended for use as vacuum tube holders that can be attached to a female Luer connector of the Saf-T Wing® winged needle or a male Luer connector of the syringe. The Saf-T Holder® blood culture device is also intended for use with a blood culture bottle.

PRECAUTIONS*

Follow the standard infection control procedures as specified by the CDC and OSHA standards (USA) or local equivalent. Do not reuse. Procedure should be performed by a trained and properly qualified person.

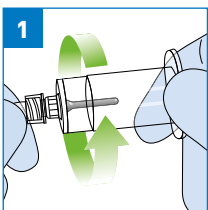
*Note: Please refer to Instructions for Use provided with the device for a full listing of the Indications and the Precautions.

Instructions For Use

Use Aseptic Technique.

Using Saf-T Holder® device with Saf-T Wing® blood set or similar devices:

1. Peel blister pouch and remove device. Firmly secure the Saf-T Holder® device to female Luer. [See Fig.1]



2. Perform venipuncture according to institutional policy.

3. Collect blood into vacuum tube by pushing tube into holder and then pushing vacuum tube stopper over needle. Hold the tube in place until blood stops flowing. Additional tubes may be used, as appropriate. A blood draw loss of approximately 0.57 mL (with 12" [30 cm] tubing) or 0.31 mL (with 6" [15 cm] tubing) may result when collecting the first tube sample.
4. After use, place sharps in a suitable sharps container. Dispose of contaminated product in a safe manner according to Centers for Disease Control and Prevention, USA and Federal/State/Local regulations (EPA, OSHA) and healthcare facility guidelines or local equivalent.



Device Components

COMPONENT COMPOSITION

- **Holder and rear Adapter:** Polypropylene
- **Multi-sample adaptor with male Luer lock:** ABS
- **Multi-sample adaptor with female Luer lock:** PVC with DINP
- **Cannula Holder:** Stainless Steel, 20G
- **Cannula Bootie:** Isoprene Rubber
- **Adhesive:** Loctite 3311
- **Lubricant:** Engineered Fluid

MANUFACTURING SITE NAME AND ADDRESS

Smiths Healthcare Manufacturing S.A. de C.V.
Ave Calidad No. 4
Parque Industrial Internacional Tijuana
Tijuana, B.C. 22425
Mexico

STERILIZATION METHOD

Smiths Medical uses a validated ethylene oxide (EO) sterilization cycle to sterilize this product. The products are for single-use only and they cannot be re-sterilized.

SHELF LIFE

A five year expiration date is assigned to the product as long as the packaging is undamaged and unopened.

LABELING AND PACKAGING

One Saf-T-Holder is packaged in a flexible, peel-open blister. Blood culture devices are packed fifty units per case. All other Saf-T-Holders are packed as four boxes of fifty units per case. The lot number, manufacturing date, and expiration date are located on all levels of packaging.

PACKAGING DIMENSIONS AND WEIGHT

Dispenser Box: 8¹/₂" x 4¹¹/₁₆" x 10¹/₄"

ORDERING INFORMATION

Saf-T Holder®		
Product Code	Description	Country of Origin
96000	Saf-T Holder® long with male Luer adapter	Mexico
96000S	Saf-T Holder® short with male Luer adapter	Mexico
96002	Saf-T Holder® with locking female Luer adapter	Mexico
96002S	Saf-T Holder® short with locking female Luer adapter	Mexico
96004	Saf-T Holder® blood culture device with male Luer adapter	Taiwan
96005	Saf-T Holder® blood culture device with locking female Luer adapter	Taiwan

For more information visit our website at www.smiths-medical.com

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Find your local contact information at: www.smiths-medical.com/customer-support

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