

Item Numbers: 781621, 781623, 781625

Rx Only | Non-pyrogenic | Latex-free | Not for use in an MRI environment

1. Intended Purpose

The Blood Collection Set is a sterile, single-use medical device intended for venous blood collection, blood collection using a syringe, and short-term intravenous (IV) administration (up to 2 hours). The device is intended to be used by trained healthcare professionals in clinical and laboratory settings.

2. Device Description

The Blood Collection Set consists of a needle with an integrated accidental needlestick prevention mechanism, flexible tubing, wings for handling, and a luer connection compatible with standard blood collection holders, syringes, and IV lines. The device incorporates a passive safety feature designed to reduce the risk of needlestick injury after use.

3. Instructions for Use

3.1 Blood Collection (Figures A–F)

1. Prior to use, inspect the packaging to ensure it is intact. Do not use the product if the packaging is damaged.
2. Verify that the Female Luer Adapter is securely connected to the Male Luer Adapter (Figure B) and that the Male Luer Adapter is securely attached to the holder.
3. Remove the needle cap.
4. Perform venipuncture in accordance with institutional procedures.

3.1.1 Needle Withdrawal and Safety Activation:

Two-Handed Method

1. Apply pressure to the insertion site using your fingers, as shown in the figures.
2. Withdraw the needle from the patient's vein.
3. Grasp the bottom of the yellow safety sheath with the thumb and index finger of one hand.
4. Using the other hand, pull downward on the tubing to retract the needle fully into the yellow safety hub.
5. An audible click indicates that the needle is locked in the safe position.

3.1.2 Needle Withdrawal and Safety Activation: One-Handed Method

1. Apply pressure to the insertion site using your fingers, as shown in the figures.
2. Withdraw the needle from the patient's vein.
3. Grasp the bottom of the yellow safety sheath with the thumb and index finger.
4. Using the same hand, wrap the remaining three fingers around the tubing and pull until the needle is fully retracted into the yellow safety hub.
5. An audible click indicates that the needle is locked in the safe position.
6. Dispose of the used device and all associated materials in an approved sharps container.
7. Wash hands in accordance with institutional procedures.

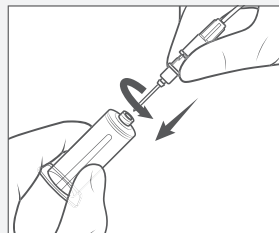


Figure A

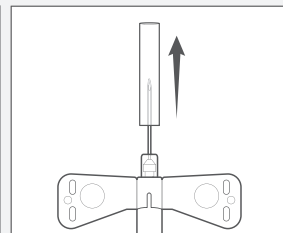


Figure B

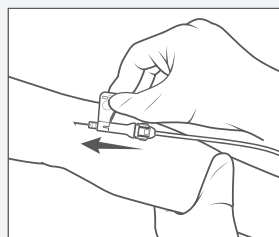


Figure C

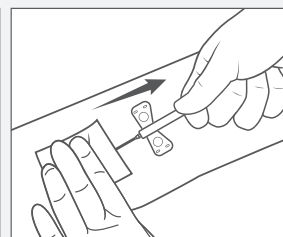


Figure D

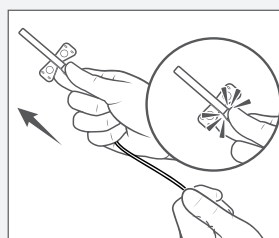


Figure E



Figure F

4. Warnings

- This device must only be used by trained healthcare professionals.
- Do not improperly release the lock, forcefully pull on the wings, or apply excessive force to the device. Such actions may damage the device and compromise safety.
- Do not attempt to deactivate, disable, or destroy the accidental needlestick prevention mechanism after activation.
- Failure to follow these instructions may result in needlestick injury or exposure to bloodborne pathogens.

5. Precautions

- Activate the safety mechanism immediately after withdrawing the needle from the patient.
- Keep hands away from the needle tip at all times during activation of the safety mechanism.
- Blood or other bodily fluids may leak from the device when disconnecting the luer connector. Use appropriate personal protective equipment and follow standard precautions.
- Do not reuse the device. Reuse may result in infection, device malfunction, or injury.
- Store the product in a clean, cool, and dry environment away from direct sunlight, excessive heat, and high humidity.

6. Single-Use Statement

This device is intended for single use only. Do not reprocess, re-sterilize, or reuse. Reuse may compromise device performance and patient or user safety.

7. Universal (Standard) Precautions

Handle all blood, body fluids, and sharps as potentially infectious in accordance with applicable regulations and institutional policies. In the event of exposure, obtain appropriate medical evaluation and follow established exposure management procedures. Dispose of all sharps in approved bio-hazard containers.



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