

**VACUETTE® Safety Blood Collection /
Infusion Set
Instructions for Use**

Intended Use

The **VACUETTE®** Safety Blood Collection/Infusion Set is used in routine blood collection procedures and/or the short-term infusion of intravenous fluids. The winged needle is designed with a safety shield, which can be activated to cover the needle immediately following blood collection/infusion to aid in the protection against accidental needlestick injury. The product is to be used by appropriately trained healthcare professionals only in accordance with these instructions.

Product Description

The **VACUETTE®** Safety Blood Collection/Infusion Set is a single-use, sterile, winged needle bonded to a flexible tubing with a luer connector. It is available in various combinations. The **VACUETTE®** Safety Blood Collection/Infusion Set is individually wrapped, sterile and can be used with a luer system (e.g. Holdex®).

VACUETTE® SAFETY Blood Collection/Infusion Sets

Type	Description
VACUETTE® Safety Blood Collection/Infusion Set	Individually wrapped and sterile allowing set to be used with a luer system.
VACUETTE® Safety Blood Collection Set with Luer Adapter	Individually wrapped and sterile with Luer Adapter. (for use with e.g. VACUETTE® Standard Tube Holder).
VACUETTE® Safety Blood Collection Set with Luer Adapter and Holder	Individually wrapped and sterile ready to be used for blood collection.
VACUETTE® Safety Blood Collection Set with HOLDEX® (this product contains dry natural rubber)	

Precautions/Cautions

Precautions

The device will perform as intended when the instructions are followed accordingly.

- Refrain from carelessly releasing the lock, or forcefully pulling the wing, as such actions may damage the integrity of the device
- Examine individual package for integrity of packaging prior to use. If packaging has been torn, do not use.
- Any used needle is considered contaminated and should be disposed of in an approved "sharps" biohazard container immediately after use.
- Do not forcefully release or re-activate the safety mechanism after it has been activated.
- Keep hands behind needle at all times during use and disposal.

Caution

- Handle all biological samples and blood collection "sharps" (lancets, needles, Luer adapters, and blood collection sets) according to the policies and procedures of your facility.
- Obtain appropriate medical attention in the case of any exposure to biological samples (for example, through a puncture injury), since they may transmit HIV (AIDS), viral hepatitis, or other infectious disease. Any used needle is considered contaminated and should be disposed of in an approved "sharps" biohazard container immediately after use.
- A reuse of the product may cause harmful infections, injury or death.
- Discard all used Safety Blood Collection Sets and Blood Collection Sets together with the Holder in biohazard containers approved for their disposal.
- Gloves should be worn at all times during venipuncture to minimize exposure hazard.
- The plasticizer DEHP is present in the fluid pathway of the Safety Infusion Set tubing. Leaching of DEHP is possible on contact with lipids. Special care has to be taken when used on pregnant or nursing women and children.
- Caution must be taken when collecting blood samples from immobilised, haemophilic or epileptic patients, for example.
- Due to the risk of surface contamination due to blood dripping from the used needle tip, it is recommended to dispose of the needle with the tip directed upwards.
- Never cover the safety mechanism with sticking tape.
- Do not attempt to tamper with the safety mechanism after activation.

Storage of VACUETTE® Safety Blood Collection/Infusion Sets before use

Store the **VACUETTE®** Safety Blood Collection/Infusion Set at 4–36°C (40–96.8°F).

NOTE: Avoid exposure to direct sunlight. Exceeding the maximum recommended storage temperature may lead to impairment of the **VACUETTE®** Safety Blood Collection/Infusion Set quality.

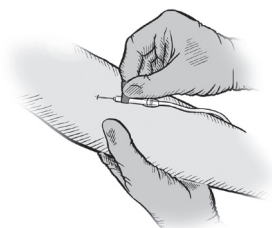
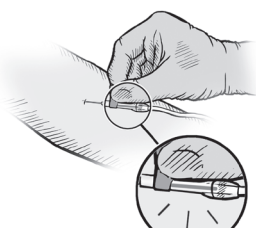

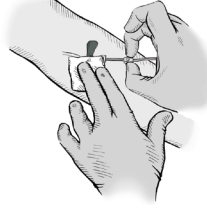

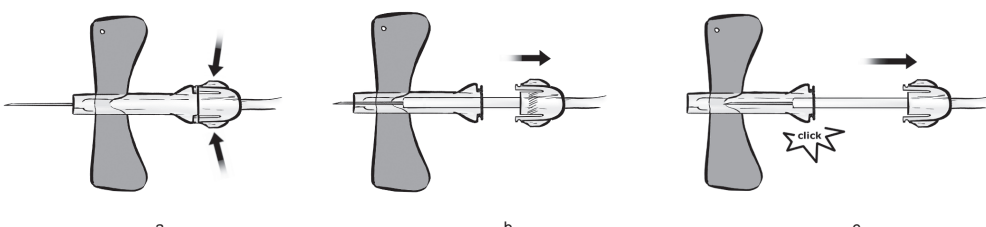
Handling of the VACUETTE® Safety Blood Collection/Infusion Sets






- If collecting a blood sample, select appropriate tube(s) and **VACUETTE®** Safety Blood Collection Set.
- Remove **VACUETTE®** Safety Blood Collection/Infusion Set from packaging. Check to make sure that the wing protector is securely locked into its safety mechanism.

NOTE: If individual packaging has been opened or tampered with, please choose another needle.

- Select site for venipuncture. Apply tourniquet and prepare site with appropriate antiseptic.

DO NOT PALPATE site after cleansing. Carefully remove needle cap from safety-winged needle.

D. Blood Collection/ Infusion		E. Activation of safety mechanism	
<p>Fig.1 Perform venipuncture with patient's arm in downward position.</p> 	<p>Fig.2 Flashback will confirm successful venipuncture. Immobilize the winged needle with tape when necessary.</p> <ul style="list-style-type: none"> • Collect blood or • Begin infusion <p>NOTE: Before connecting infusion line, remove cap from female luer adapter.</p> 	<p>Fig.3 After completion of blood collection/infusion, hold the gauze down with one hand. With the other hand, activate the safety mechanism by pressing in both sides of the hub to engage the lock.</p> <p>NOTE: Do not apply undue pressure to the puncture site.</p> 	<p>Fig.4 Slide the safety mechanism backward until an audible click is heard. The click is a sign that the safety mechanism has been correctly activated.</p> <p>NOTE: Maintain pressure on the puncture site according to facility protocol.</p> 
<p>F. Disposal</p> <p>Fig.5 Promptly dispose of VACUETTE® Safety Blood Collection/Infusion Set in an approved disposal container in accordance with the procedures of your facility.</p> 	<p>Activation of safety mechanism (detail)</p> <p>It is recommended to activate the safety mechanism when the blood collection/infusion has been completed and the VACUETTE® Safety Blood Collection/Infusion Set is in the patient's vein.</p> <p>NOTE: Do not apply undue pressure to the puncture site.</p> <ol style="list-style-type: none"> Activate the safety mechanism by pressing in both sides of the hub with one hand to release the lock. Slide the hub backward. An audible click is heard when the safety mechanism has been correctly activated. Verify that the safety mechanism is secured against the wing protector. The needle will be completely retracted into the wing protector. <p>NOTE: Maintain pressure on the puncture site according to facility protocol.</p> 		

<p>Label information:</p> <p> Item number</p> <p> Lot number: Batch number</p> <p> Expiry Date: Product can be used until the end of the month indicated</p> <p> Symbol for "sterilisation with ethylene oxide gas"</p> <p> Symbol for "single use only"</p>	<p>References:</p> <p>CLSI (Clinical and Laboratory Standards Institute) H3-A6 Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Sixth Edition</p>
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