

VACUETTE® EVOPROTECT SAFETY Blood Collection/Infusion Set Instructions for use

Intended Use

The **VACUETTE®** EVOPROTECT SAFETY Blood Collection/Infusion Set is indicated for venous blood collection and / or the short-term infusion of intravenous fluids. It is to be used by appropriately trained healthcare professionals in accordance with the instructions.

Product Description

The **VACUETTE®** EVOPROTECT SAFETY Blood Collection/Infusion Set is a single-use, sterile, winged needle bonded to flexible tubing with a luer connector and a semi-automatic release safety mechanism. The winged needle is designed with a safety mechanism, which allows for one-handed activation ensuring the needle is covered immediately following venipuncture and/or infusion to aid in the protection against accidental needlestick injury.

It is available in various combinations. The **VACUETTE®** EVOPROTECT SAFETY Blood Collection/Infusion Set is individually wrapped, sterile and can be used with a luer system (e.g. HOLDEX®).

VACUETTE® EVOPROTECT SAFETY Blood Collection /Infusion Set	Individually wrapped and sterile allowing set to be used with a luer system.
VACUETTE® EVOPROTECT SAFETY Blood Collection Set + Luer Adapter	Individually wrapped and sterile with Luer Adapter (for use with e.g. Standard Tube Holder).
VACUETTE® EVOPROTECT SAFETY Blood Collection Set + Holder	Individually wrapped and sterile ready to be used for blood collection.

The **VACUETTE®** EVOPROTECT SAFETY Blood Collection/Infusion Set is not made with natural rubber latex or DEHP.

Procedure

1. Remove **VACUETTE®** EVOPROTECT SAFETY Blood Collection/Infusion Set from packaging.
2. Check to make sure that the device is not damaged.
NOTE: If individual packaging has been opened or tampered with, please choose another device.

For Blood Collection

1. Select site for venipuncture. Apply tourniquet and prepare site with appropriate antiseptic. **DO NOT PALPATE SITE AFTER CLEANSING.**
2. Select appropriate tube(s) and **VACUETTE®** EVOPROTECT SAFETY Blood Collection/Infusion Set and, if necessary, connect it to the desired collection system.
3. Carefully remove needle cap from safety-winged needle.
4. Perform venipuncture by holding product either by the wings or by the body of the device just behind the wings with patient's arm in downward position. Flashback will confirm successful venipuncture, depending on the patient's venous pressure.
5. Immobilize the winged needle when necessary.
6. Collect blood according to your facility's procedure. REMOVE TOURNIQUET AS SOON AS BLOOD APPEARS IN TUBE. Always hold in place by pressing the tube with the thumb to ensure complete vacuum draw. **NOTE:** The first tube in the series will be under-filled due to the dead volume of the flexible tubing. A discard tube (no-additive) is recommended to be drawn prior to ensure the proper anticoagulant to blood ratio.
7. After completion, place gauze over collection site without applying pressure.
8. The product is intended for in-vein activation. With one hand, activate the safety mechanism by pressing the blue-colored release buttons. TAKE CARE NOT TO HINDER THE AUTOMATIC RETRACTION.
9. The safety mechanism will slide backwards until an audible click is heard. The click is a sign that the safety mechanism has been correctly activated.
10. Apply gentle pressure to the puncture site using the gauze pad according to facility protocol.
11. Promptly dispose of **VACUETTE®** EVOPROTECT SAFETY Blood Collection/Infusion Set in an approved disposal container in accordance with the procedures of your facility.

For short-term IV Infusion (without prior blood collection)

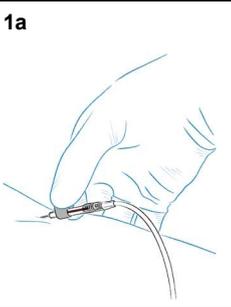
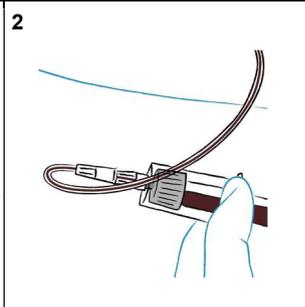
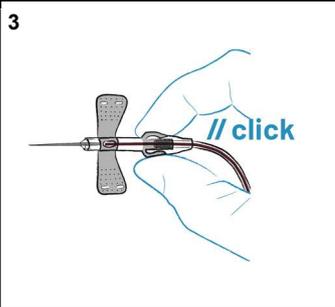
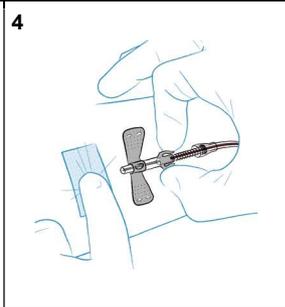
For infusion purposes, aseptically remove any male device (Luer Adapter or Luer Adapter + Holder), if present, from the set prior to connection to the female luer port.

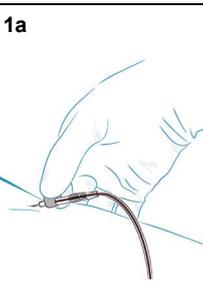
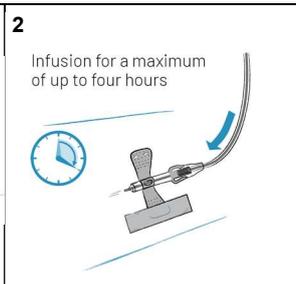
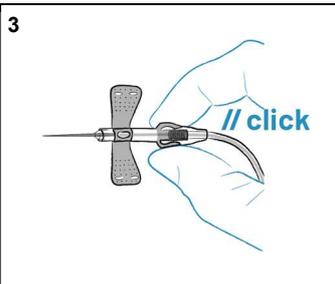
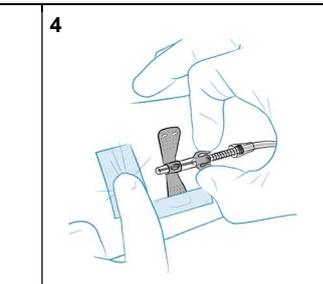
Carefully remove needle protective cap from safety-winged needle. Prime set in accordance with the policies and procedures of your facility. Make sure that there is no air in the system during infusion.

*Maximum Priming Volume (ml)				*Maximum Flow Rate (ml/min)			
Tubing	21G	23G	25 G	Tubing	21G	23G	25 G
10 cm / 4 inch	0.21	0.21	0.21	10 cm / 4 inch	19	13	4.5
19 cm / 7.5 inch	0.33	0.33	0.33	19 cm / 7.5 inch	19	13	4.5
30 cm / 12 inch	0.46	0.46	0.46	30 cm / 12 inch	19	13	4.5

*approximated values established with water

1. Unless blood collection has been carried out beforehand and the needle remains within the vein, perform venipuncture by holding product either by the wings or by the body of the device just behind the wings with patient's arm in downward position. Assure that the infusion set is securely attached to the patient. Ensure that the safety mechanism is not covered with tape.
2. Begin short term IV infusion.
NOTE: Please follow your facility's procedures. However, it is recommended that the device be used for single infusion purposes for a maximum of 4 hours.
3. After completion of infusion, place the gauze over the insertion site without applying pressure and terminate the procedure (see points 8-11 under blood collection above).

Blood Collection: In-Vein Activation of Safety Mechanism				
When the blood collection has been completed and no subsequent infusion is intended, it is recommended to activate the safety mechanism while the VACUETTE® EVOPROTECT SAFETY Blood Collection/Infusion Set is still in the patient's vein.				
				
<p>1a OR 1b. Perform venipuncture by holding product either by the wings or by the body of the device just behind the wings (with patient's arm in downward position). Take care not to obstruct the safety mechanism of the device. Flashback will confirm successful venipuncture, depending on the patient's venous pressure.</p>		<p>2. Immobilize the wings when necessary. Collect blood according to your facility's procedure.</p>	<p>3. After completion, place gauze over collection site without applying pressure. The product is intended for in-vein activation. With one hand, activate the safety mechanism by pressing the blue colored release buttons. TAKE CARE NOT TO HINDER THE AUTOMATIC RETRACTION. The safety mechanism will slide backwards until an audible click is heard. The click is a sign that the safety mechanism has been correctly activated.</p>	<p>4. Apply gentle pressure to the puncture site using the gauze pad according to facility protocol. Dispose of device in a sharps container per facility procedure.</p>

Short term Infusion: In-Vein Activation of Safety Mechanism				
When the infusion has been completed, it is recommended to activate the safety mechanism while the VACUETTE® EVOPROTECT SAFETY Blood Collection/Infusion Set is still in the patient's vein.				
				
<p>1a OR 1b. Perform venipuncture by holding product either by the wings or by the body of the device just behind the wings (with patient's arm in downward position). Take care not to obstruct the safety mechanism of the device. Flashback will confirm successful venipuncture, depending on the patient's venous pressure.</p>		<p>2. Assure that the infusion set is securely attached to the patient. Ensure that the safety mechanism is not covered with tape. Begin short term IV infusion for a maximum of up to 4 hours.</p>	<p>3. After completion, place the gauze over the insertion site without applying pressure. The product is intended for in-vein activation. With one hand, activate the safety mechanism by pressing the blue colored release buttons. TAKE CARE NOT TO HINDER THE AUTOMATIC RETRACTION. The safety mechanism will slide backwards until an audible click is heard. The click is a sign that the safety mechanism has been correctly activated.</p>	<p>4. Apply gentle pressure to the puncture site using the gauze pad according to facility protocol. Dispose of device in a sharps container per facility procedure.</p>

Precautions/Cautions

- 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 prior to use. If packaging has been damaged or unintentionally opened before use, do not use.
 - Do not use the product after the expiration date.
 - Any used needle is considered contaminated. Discard all used sets in biohazard containers approved for their disposal.
 - Do not forcefully release or re-activate the safety mechanism after it has been activated.
 - Do not bend the needle. Bending the needle can cause pain to the patient, can cause needlestick injuries, can lead to contamination of the needle causing infections, can lead to haemolysis of the sample, or can cause damage of the steel tubing and needle tip.
 - Keep hands behind needle at all times during use and disposal.
 - It is recommended to activate the safety mechanism while the **VACUETTE®** EVOPROTECT SAFETY Blood Collection/Infusion Set is still in the patient's vein to avoid blood or IV fluid droplets.
 - Do not use for subcutaneous infusion or injection.
 - 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.
 - Do not reuse. Reuse of the product may cause harmful infections or injury.
 - Gloves should be worn at all times during venipuncture to minimize exposure hazard.
 - Avoid blood leakage and any air in the tubing during infusion procedure or when changing from blood collection to infusion.
 - Caution must be taken when collecting blood samples from immobilized, haemophilic or epileptic patients.
 - Due to the risk of surface contamination from residual blood that may be on the needle tip, it is recommended to dispose of the needle following activation of the safety activation mechanism with the tip directed upwards.
 - Never cover the safety mechanism with adhesive tape.
 - IV infusion procedures should be done according to the policies and procedures of your facility.
 - For hygienic changing of accessories, avoid blood leakage and follow the instructions of your facility.
 - Make sure all air is removed by priming prior to use as short-term IV infusion device.
 - If blood collection and infusion are done with the same set, the infusion must follow the blood collection immediately.
 - Prior to infusion, make sure that there are no clots in the system.
 - Do not collect blood after infusion.
- Only applicable for member states of the European Union: Should any serious incidents occur in relation to the product, these must be reported to the manufacturer and the competent authority in the member state, in which the user/patient is established.
 - Only applicable for Saudi Arabia: Should any serious incidents occur in relation to the product, these must be reported to the manufacturer and the Saudi Food and Drug Authority (SFDA).

Storage before use

Store at 4–25°C (40–77°F).

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

Label information

	Manufacturer		Temperature limit	Rx Only (USA)	Prescription device
	Use-by date		Do not re-use		Medical device
	Batch code		Do not use if package is damaged and consult instructions for use		Keep away from sunlight
	Catalogue number		Consult instructions for use		Date of manufacture
	Sterilized using irradiation		Single sterile barrier system		Authorized representative in Switzerland

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician.

Literature:
CLSI GP41, 7th Edition Collection of Diagnostic Venous Blood Specimens

 Greiner Bio-One GmbH
Bad Haller Str. 32
4550 Kremsmünster
Austria

Made in Austria

www.gbo.com/preanalytics
office@at.gbo.com
Phone +43 7583 6791

 Greiner Bio-One Vacuette Schweiz GmbH
St. Leonhardstraße 39
9000 St. Gallen, Switzerland