

VACUETTE® QUICKSHIELD Complete PLUS (with rotational shield) Instructions for use

Intended Use / Indications for use

The **VACUETTE®** QUICKSHIELD Complete PLUS is intended to be used only with **VACUETTE®** Blood Collection Tubes as a system in routine venipuncture procedures. This device is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury. **VACUETTE®** VISIO PLUS Needles are designed for use in the daily blood collection routine when delegated by a qualified practitioner. The flashback window is situated in the transparent part of the cannula hub, which assists the user to recognize successful vein penetration. They are for single-use only and should only be used by adequately trained healthcare personnel in accordance with the instructions.

It is a blood collection needle with flashback window with a preassembled tube holder and safety shield. The sterile device is intended for use in healthcare settings such as hospitals, clinics, and laboratories on patients requiring venous blood sampling, including pediatric, adult and elderly populations. The needle is inserted into a peripheral vein suitable for venipuncture to establish venous access, allowing for blood collection for in vitro diagnostic testing.

Product Description

The sterile **VACUETTE®** QUICKSHIELD Complete PLUS is a single packed **VACUETTE®** QUICKSHIELD Safety Tube Holder with pre-threaded **VACUETTE®** VISIO PLUS Blood Collection Needle in a blister pack. It is a sterile, single-use plastic tube holder, designed with a safety shield, which can be activated to cover the needle immediately following venipuncture.

Precaution / Cautions

- This device is specifically designed and intended for use in combination with other Greiner Bio-One products. Its safety and performance have not been confirmed when used with devices from other manufacturers.
- Visually inspect for breaches of sterile packaging integrity immediately prior to use. Do not use if packaging is damaged or unintentionally opened before use.
- Do not use the product after its expiration date.
- Do not bend or recap needle.
- Do not use if storage conditions were exceeded.
- Practice standard precautions. Key elements include hand hygiene, use of personal protective equipment and maintaining a thorough and clean work environment.
- After venipuncture, dispose of used needle with **VACUETTE®** QUICKSHIELD Complete Plus as one unit in appropriate sharps container in accordance with policies and procedures of your facility.
- Always keep hands behind the needle to prevent needlestick injuries.
- Any **VACUETTE®** QUICKSHIELD Complete PLUS that becomes contaminated with blood is considered hazardous and must be disposed of immediately.
- Handle all biological samples and blood collection sharps according to the policies and procedures of your facility.
- Obtain appropriate medical attention in the event of any exposure to biological samples (for example, through a puncture injury), since these samples may transmit HIV, viral hepatitis or other infectious disease.
- Do not resterilize the product.
- Do not reuse the product. A reuse of the product may cause a severe infection.
- Do not manipulate the activated safety mechanism.
- This device is specifically designed and intended for use in combination with other Greiner Bio-One products. Its safety and performance have not been confirmed when used with devices from other manufacturers.
- This device contains the following substance classified as CMR 1B, in a concentration exceeding 0.1% by weight: Cobalt, CAS Number 7440-48-4 and EC Number 231-158-0. Current scientific evidence indicates that medical devices made from cobalt alloys or stainless steel alloys containing cobalt do not pose an increased risk of cancer or adverse reproductive effects.
- Despite compliance with applicable safety standards and the implementation of risk control measures, potential adverse events associated with blood collection and/or infusion - such as, but not limited to, discomfort, hematoma, pain, infection, hemolysis, hemoconcentration, vein or tissue damage, thrombosis, phlebitis, allergic reactions, improper diagnosis or treatment, vasovagal episodes, syncope, diaphoresis, or air embolism - may still occur due to patient-specific factors, the chosen venipuncture site, device malfunction, and/or the clinical technique, handling, or experience of the healthcare professional.

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).

Needle Gauge Selection

Selecting the correct needle gauge is essential for patient comfort, minimizes complications, and preserves specimen integrity. Following best practices should be followed:

- Assess vein size and condition before needle selection.
- Use the largest gauge suitable for the patient's vein to ensure optimal flow and sample integrity.
- Follow institutional and healthcare protocols for safe blood collection.

Gauge Recommendations

- **21G:** Suitable for adults and preferred for healthy veins. Preferred for optimal flow and minimal hemolysis risk.^{1,2}
- **22G:** Suitable for adults and patients with smaller or fragile veins, including elderly and pediatric patients.³
- If vein conditions require smaller gauges (23G or 25G) other Greiner Bio-One winged products can be used (**VACUETTE®** EVOPROTECT SAFETY Blood Collection/Infusion Set or SAFETY Blood Collection/Infusion Set).

¹ CLSI GP41, 7th Edition (2017), Collection of Diagnostic Venous Blood Specimens

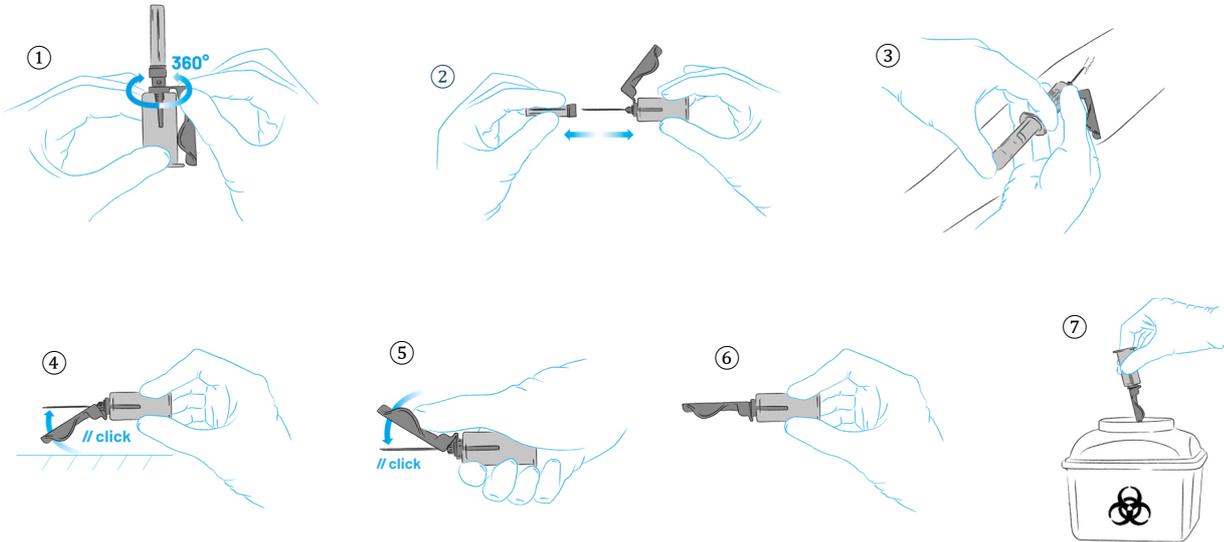
Storage conditions

Store products between 4–36°C (40–97°F).

NOTE: Avoid exposure to direct sunlight. Exceeding the maximum recommended storage temperature may lead to impairment of the product.

Handling

1. Open the blister packaging and remove the device.
2. The dot on the needle cap indicates the orientation of the bevel.
3. Rotate the shield to the preferred position where it remains stable during venipuncture ①.
4. Select the puncture site, apply the tourniquet (max. 1 minute), and prepare with antiseptic. Do not palpate after cleansing.
5. Place the patient's arm downward, remove the needle cap, and perform the venipuncture with the tube cap upper-most ②.
6. Insert the tube into the **VACUETTE**[®] QUICKSHIELD Complete PLUS, puncturing the rubber diaphragm ③. Center the tube to prevent vacuum loss.
7. Remove the tourniquet as soon as blood starts flowing. Do not turn the tube upside down during blood draw. Hold the tube with your thumb to ensure vacuum draw.
8. Place each subsequent tube in the holder. Avoid contact between the tube contents and the cap or needle tip during blood collection.
9. When blood stops flowing into the last tube, remove the needle and apply pressure with a sterile swab until bleeding stops.
10. Immediately after removing the needle, activate the safety shield. Press the shield towards the needle on a stable surface ④ or use your thumb or finger ⑤, keeping them behind the shield to prevent needle stick injuries ⑥. An audible click ensures the safety shield is activated.
11. Apply a plaster or bandage if desired.
12. Dispose of the used needle with **VACUETTE**[®] QUICKSHIELD Complete PLUS in an appropriate disposal device ⑦.



Label Information

	Manufacturer		Sterilized using irradiation		Do not use if package is damaged
	Use-by date		Do not re-use		Date of manufacture
	Batch code		Consult instructions for use		Medical device
	Catalogue number		Temperature limit		Prescription device
	Keep away from sunlight		Single sterile barrier system		Authorized representative in Switzerland
	Do not re-sterilize		Contains hazardous substances: Cobalt		Non-pyrogenic
	Unique device identifier		CE marking: Signifies European technical conformity		Made in Austria
	Fragile		This way up		Keep dry
	Open here				

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



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