

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

Intended 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 these instructions.

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

1. If the sterile packaging is damaged or unintentionally opened before use, the product must not be used and must be disposed of.
2. Do not use **VACUETTE®** QUICKSHIELD Complete PLUS when damaged.
3. Any **VACUETTE®** QUICKSHIELD Complete PLUS that becomes contaminated with blood is considered hazardous and must be disposed of immediately.
4. Do not recap needle.
5. Do not bend needle.
6. After venipuncture, dispose of used needle with **VACUETTE®** QUICKSHIELD as one unit in appropriate sharps container in accordance with policies and procedures of your facility.
7. Keep hands behind needle at all times during use and disposal.
8. Handle all biological samples and blood collection sharps according to the policies and procedures of your facility.
9. 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.
10. Discard all blood collection "sharps" in biohazard containers approved for their disposal.
11. Gloves should be worn at all times during venipuncture to minimize exposure hazard.

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.

Storage before use

Store holders at 4–36°C (40–97°F).

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

Handling

READ THIS ENTIRE CIRCULAR BEFORE PERFORMING VENIPUNCTURE.

WEAR GLOVES DURING VENIPUNCTURE AND WHEN HANDLING BLOOD COLLECTION TUBES TO MINIMISE EXPOSURE HAZARD!

1. Open the blister packaging and fully remove device from packaging.

NOTE: The blister packaging is an indicator of sterility and product integrity. If the blister packaging is broken or damaged, dispose of the **VACUETTE®** QUICKSHIELD Complete PLUS and select another.

NOTE: Do not bend needles or use **VACUETTE®** QUICKSHIELD Complete PLUS when needle is bent.

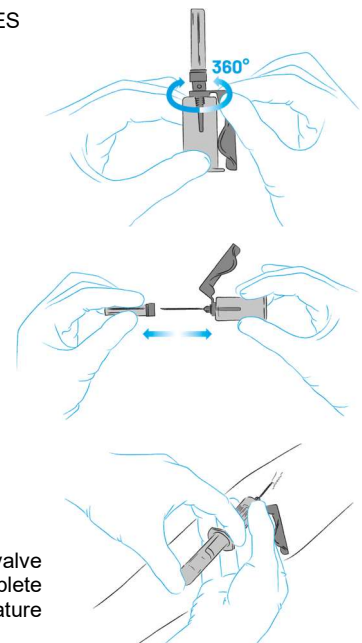
The dot on the needle cap indicates the location of the bevel.

2. The shield can be rotated to the preferred position on the holder where it remains stable during venipuncture.

3. Select the puncture site. Apply the tourniquet (max. 1 minute). Prepare the venipuncture site with appropriate antiseptic. Do not palpate the venipuncture area after cleansing!

4. Place the patient's arm in a downward position. Remove the needle cap. Perform the venipuncture, with the patient's arm downward and the tube cap upper-most.

5. Push the tube into the **VACUETTE®** QUICKSHIELD Complete PLUS and onto the needle valve puncturing the rubber diaphragm. Center tubes in the **VACUETTE®** QUICKSHIELD Complete PLUS when penetrating the cap to prevent sidewall penetration and subsequent premature vacuum loss.



- Remove the tourniquet as soon as blood appears in the tube. Do not allow the contents of the tube to contact the cap or the end of the needle during the procedure, i.e. under no circumstances should the tube be turned upside down during the procedure. Always hold in place by pressing the tube with the thumb to ensure complete vacuum draw.

NOTE: Blood may occasionally leak from the needle sleeve. Practice universal safety precautions to minimize hazard exposure.

- Place succeeding tubes in the holder. Ensure that the contents of the tube do not come into contact with the cap or the needle tip during blood collection.
- As soon as blood stops flowing into the last tube, carefully remove the needle from the vein, applying pressure to the puncture site with a dry sterile swab until bleeding stops. Once clotting has occurred, apply an adhesive plaster or bandage if desired.

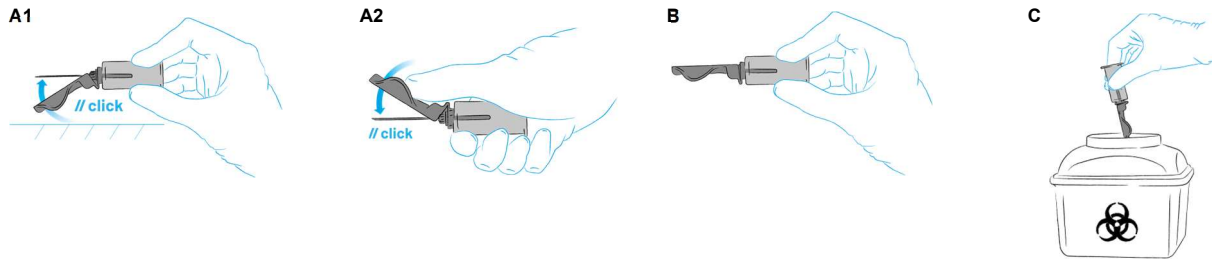
Do not recap the needle! Recapping of needles increases the risk of needlestick injury.

NOTE: After venipuncture, the top of the cap may contain residual blood. Take proper precautions when handling tubes to avoid contact with this blood.

Activation of safety shield

Immediately after removing needle from the vein, the following procedures are used to activate the safety shield to prevent needlestick injury.

- Activate the safety shield by gently pressing the shield towards the needle on a stable surface. Activation with a thumb or finger is also possible, whereby the thumb and finger should remain behind the shield at all times. (See A1/A2)
- An audible click is heard ensuring the user the safety shield has been properly and fully activated. The risk of a needlestick injury is thus virtually eliminated. (B)
- Dispose of the used needle with **VACUETTE® QUICKSHIELD Complete PLUS** in an appropriate disposal device. (C)



NOTE: Do not forcefully release or re-activate the safety mechanism after it has been activated.

Disposal

The general hygiene guidelines and legal regulations for the proper disposal of infectious material should be considered and followed. Disposable gloves may prevent the risk of infection. Contaminated holders must be disposed of immediately after blood collection in suitable biohazard disposal containers, which can then be autoclaved and incinerated.

Label Information

	Manufacturer		Sterilized using irradiation		Do not use if package is damaged and consult instructions for use
	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

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

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