



## Why do we need VACUETTE® Safety Products?

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### EDITORIAL

A needlestick injury is a common event in the healthcare environment. When drawing blood, administering medication, or performing other procedures involving sharps, the needle can slip and injure the healthcare worker or the patient.

*Thus viruses are easily transmitted from a source person.*

These injuries also commonly occur during **needle recapping** and as a result of **failure to dispose of used needles in approved sharps containers**.

If a surgical needle inadvertently penetrates the glove and skin of the surgeon or assistant, this is a penetration incident, and should the surgeon or assistant be injured with the scalpel or other sharp instrument, this is also handled as a needlestick injury. Generally needlestick injuries cause only minor bleeding or visible trauma, however, even in the absence of bleeding **the risk of viral infection remains**.

Scalpel injuries tend to be larger than a needlestick. In turn, a needlestick injury may also pose a risk for a patient if the injured health professional carries any pathogens. Needlestick injuries are not limited to the medical community. Any environment where sharps are encountered poses a risk. Therefore, these events are of concern because of the risk of transmitting blood-borne diseases through the passage of the hepatitis B virus (HBV), the hepatitis C virus (HCV) and the Human Immunodeficiency Virus (HIV), the virus which causes AIDS as well as those causing viral haemorrhagic fevers (Crimean Congo haemorrhagic fever, Ebola, Lassa and Marburg) and dengue, just to mention the most dangerous

ones. Syphilis and malaria may also be transmitted via contaminated blood.

**Injuries of this kind have to be averted by correct prevention!**

Appropriate supplies and protective equipment are available on the market.

However, venipuncture practice of the invasive procedure varies considerably between countries, and between institutions and individuals within the same country.

To simplify the application and to increase patient and user safety all **VACUETTE®** Safety Products fulfil the following requirements:

- The safety mechanism must be an integral part of the system, and compatible with other accessories
- One handed activation of the safety mechanism must be possible
- The safety mechanism must be activated immediately after use
- The safety mechanism must prevent re-use
- It should not be necessary to change application technique
- A clear signal, either acoustic or tangible, must indicate to the user correct activation of the safety mechanism

These above listed requirements of Safety Products are already demanded by law in the USA and several European countries.

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The **VACUETTE®** Safety Product line includes:

- **VACUETTE®** QUICKSHIELD Safety Tube Holder
- **VACUETTE®** QUICKSHIELD Complete (PLUS)
- **VACUETTE®** PREMIUM Tube
- **MiniCollect®** Safety Lancets
- Safety Blood Collection/Infusion Sets
- **TIPGUARD** Safety Tube Holder

### PRODUCT STUDIES

The **VACUETTE®** QUICKSHIELD Safety Tube Holder is a single-use safety evacuated blood collection tube holder. It is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to help protect against accidental needlestick injury. The QUICKSHIELD holder is used in conjunction with **VACUETTE®** Multiple Use Drawing Needles and VISIO PLUS Needles.

A clinical evaluation was carried out to evaluate the performance of the **VACUETTE®** QUICKSHIELD Safety Tube Holder to evaluate the device's performance in simulated blood drawing procedures. Simulated blood drawing was performed by 50 medical professionals, including 15 doctors, 10 nurses, 11 medical technologists, 14 phlebotomists, testing 10 devices each for a total of 500 devices. Each user was asked to complete a questionnaire to evaluate the product.

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The questionnaire included the following areas of application:

- ease of use
- safety
- compatibility
- overall safety mechanism

The user was asked to answer each question according to a five-graded system:

**1** – Strongly Agree, **2** – Agree, **3** – Neutral, **4** – Disagree, **5** – Strongly Disagree and **6** – Not Applicable.



The **VACUETTE®** QUICKSHIELD Safety Tube Holder scored acceptably on all questions regarding safety mechanism and the overall safety of the device. There were no failures of the safety shield to activate properly or to safely cover the needle. The **VACUETTE®** QUICKSHIELD Safety Tube Holder can therefore be considered to be a “safety medical device” that is appropriate and effective.

Additionally, to meet the high quality demands on **VACUETTE®** QUICKSHIELD Safety Tube Holder, functional tests for random devices are carried out internally. This includes testing if the needle locks into the protection sleeve properly and the safety shield activates fully. Additionally the impermeability of the rubber sleeves is an important part of the visual examination.

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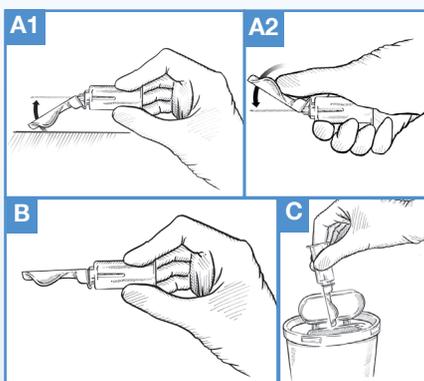
Introducing Eva Steindl, from the product management department, our clinical studies coordinator.

References:

- Greiner Bio-One Internal Study. VG-06IN126 – Long term stability test Quickshield
- Greiner Bio-One Internal Study. VG-07IN145 – Long term stability test Quickshield Complete
- Greiner Bio-One External Study (White Paper). USA-13 – Evaluation of VACUETTE QUICKSHIELD Safety Tube Holder Evaluation
- Greiner Bio-One Prüfanweisung. PA 10.01.05-42 Rev 01. Gültig ab 06. Juli 2000

## TROUBLESHOOTER

### VACUETTE® QUICKSHIELD Safety Tube Holder



#### 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.

1. Activate the safety shield by gently pressing the shield towards the needle on a stable surface. Thumb activation is also possible, whereby the thumb should remain behind the shield at all times. (See A1/A2)
2. An audible click is made ensuring the user the safety shield has been properly and fully activated. (B)
3. Dispose of the used needle with **VACUETTE®** QUICKSHIELD Safety Tube Holder in an appropriate disposal device. (C)

### Safety During Disposal

1. Disposal containers must be replaced routinely and not overfilled (only fill to 75% of capacity).
2. The frequency with which disposal boxes should be disposed of depends on the amount of medical waste generated by the institution.
3. Some facilities may already have sharps collection programs established. Talk with the responsible person about this service.
4. Do not put your hands into a box.
5. Do not forcefully press objects into the box.
6. Do not compress the filled box in any way from the outside.
7. Connect box with the recommended wall holder or stick-on unit to prevent an accident.
8. Never press the box against your own body.
9. Place objects of disposal only into boxes that are big enough to hold it.
10. Never close the box with force and only use your hands to close it.

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