SAFETY Blood Collection Set + Blood Culture Holder

(non-DEHP)

Instructions for use

Intended Use: The SAFETY Blood Collection Set + Blood Culture Holder are used in routine venipuncture procedures. The winged needle of the SAFETY Blood Collection Set is designed with a safety shield, which can be activated to cover the needle immediately following blood collection to aid in the protection against accidental needlestick injury. The Blood Culture Holder is used to fill blood into blood culture bottles and tubes.

Product description: The SAFETY Blood Collection Set + Blood Culture Holder are single-use, sterile, winged blood collection needles bonded to a flexible tubing with a pre-attached Blood Culture Holder. The design of the holder allows collection of blood into blood culture bottles and VACUETTE Blood Collection Tubes. This device is non-DEHP and has no components made of natural rubber latex. The product is to be used by appropriately trained healthcare professionals only in accordance with these instructions.

Handling

- Clean the puncture site and your hands according to your facility’s approved procedures.
- Disinfect the exposed septa of the blood collection bottles with an alcohol pad and allow it to dry.
- Perform venipuncture with patient’s arm in downward position. Blood culture bottles and blood collection tubes should be maintained in an upright position during collection.
- NOTE: Follow the manufacturer’s instructions for the correct handling of blood culture bottles.
- Hold the Blood Culture Holder down on the bottles and press it down. When using an aerobic and anaerobic bottle, inoculate first the aerobic and then the anaerobic bottle.
- After obtaining the correct amount of blood, move the holder away from the bottles and (if required) continue with blood collection into VACUETTE Blood Collection Tubes.
- After completion of blood collection, hold the gauze down with one hand.
- Activate the safety mechanism by pressing in both sides of the hub to engage the lock. Slide the safety mechanism backward until an audible click is heard. The click is a sign that the safety mechanism has been correctly activated.
- Dispose of the device with Blood Culture Holder as one unit in appropriate sharps container in accordance with policies and procedures of your facility.
- NOTE: Keep hands behind needle at all times during use and disposal.
- Maintain pressure on the puncture site according to facility protocol.
- NOTE: Do not apply undue pressure to the puncture site.

VACUETTE Precautions/Cautions

- Check SAFETY Blood Collection Set + Blood Culture Holder before use. Do not use SAFETY Blood Collection Set and Blood Collection Set + Blood Culture Holder when damaged.
- Any SAFETY Blood Collection Set + Blood Culture Holder that becomes contaminated with blood is considered hazardous and must be disposed of immediately.
- Do not reshield the needle of SAFETY Blood Collection Set.
- Do not forcefully release or re-activate the safety mechanism on the SAFETY Blood Collection Set after it has been activated.
- After venipuncture, dispose of used needle with SAFETY Blood Collection Set + Blood Culture Holder as one unit in appropriate sharps container in accordance with policies and procedures of your facility.
- Keep hands behind needle at all times during use and disposal.
- 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 together with the holder in biohazard containers approved for their disposal.
- Gloves should be worn at all times during venipuncture to minimize exposure hazard.
- 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

Store product at 4°C (39°F).

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

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 products with needles must be disposed of immediately after blood collection in suitable biohazard disposal containers, which can then be autoclaved and incinerated.

Label Information

- Catalogue number
- Batch code
- Use-by-date (Use by the end of the month indicated)
- Sterilized using ethylene oxide
- Manufacturer
- Do not re-use
- Consult instructions for use

References

CLSI (Clinical Laboratory Standard Institute)
- HB-AB Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Sixth Edition
- M47-A Principles and Procedures for Blood Cultures; Approved Guideline

Caution: US Federal law restricts this device for sale by or on the order of a physician.

Production location:
- Nipro (Thailand) Corporation Ltd., 10/2 Miao 8 Bangnomko, Sana, Phra Nakhon Si Ayudhya 13110, Thailand
- Made in Thailand, distributed by Greiner Bio-One GmbH, Austria
- Greiner Bio-One GmbH, Bad Helfer Str. 32, 8550 Kremmenminder, Austria

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