

SAFETY Blood Collection Set + Blood Culture Holder
Instructions for use

Intended Use

The SAFETY Blood Collection Set + Blood Culture Holder is 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 is a single-use, sterile, winged blood collection needle 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. These products are not made with natural rubber latex. This device is to be used by properly trained healthcare professionals only in accordance with these instructions.

Precautions/Cautions

- Check SAFETY Blood Collection Set + Blood Culture Holder before use. Do not use SAFETY Blood Collection Set + Blood Culture Holder when damaged.
- Do not use SAFETY Blood Collection Sets + Blood Culture Holder after their expiration date.
- Any SAFETY Blood Collection Set + Blood Culture Holder that becomes contaminated with blood is considered hazardous and must be disposed of immediately.
- Refrain from carelessly releasing the lock, or forcefully pulling the wing, as such actions may damage the integrity of the device
- Do not recap the needle of SAFETY Blood Collection Set. Recapping of needles increases the risk of needlestick injury and harmful infections.
- 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.
- 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.
- 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.
- Do not reuse. 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 4–36°C (40–97° F).

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

Handling

- 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 air 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.
- Place the Blood Culture Holder onto the bottle and press it down.
- After obtaining the correct amount of blood, move the holder away from the bottle and (if required) continue with blood collection into a further blood culture bottle or VACUETTE® Blood Collection Tubes.
- After completion of blood collection, gently place gauze over collection site without applying pressure.
- With one hand, activate the safety mechanism of the SAFETY Blood Collection Set 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.
- Apply gentle pressure to the puncture site using the gauze pad according to facility protocol.
NOTE: Do not apply undue pressure to the puncture site.
- 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.

Disposal

- The general hygiene guidelines and legal regulations for the proper disposal of infectious material should be considered and followed.
- Disposable gloves should be worn to avoid 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

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|---|---------------------|---|---------------------------------|
|  | Manufacturer |  | Temperature limit |
|  | Use-by date |  | Do not re-use |
|  | Batch code |  | Sterilized using ethylene oxide |
|  | Catalogue number |  | Consult instructions for use |
|  | Date of manufacture | | |

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

Literature:

CLSI. *Collection of Diagnostic Venous Blood Specimens*. 7th ed. CLSI standard GP41. Wayne, PA: Clinical and Laboratory Standards Institute; 2017.
CLSI. *Principles and Procedures for Blood Cultures; Approved Guideline*. CLSI document M47-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2007.

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