

Intended Use

The SAFETY Blood Collection/Infusion Set is a single-use, sterile, winged blood collection needle bonded to a flexible tubing with a luer connector. The SAFETY Blood Collection/Infusion Set is used for blood collection and/or the short-term infusion of intravenous fluids. The winged needle 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.

Product Description

The SAFETY Blood Collection/Infusion Set is a single-use, sterile, winged needle bonded to a flexible tubing with a luer connector. It is available in various combinations. The SAFETY Blood Collection/Infusion Set is individually wrapped, sterile and can be used with a luer system (e.g. HOLDEX®). The product is to be used by appropriately trained healthcare professionals only in accordance with these instructions.

SAFETY Blood Collection/Infusion Set	Individually wrapped and sterile allowing set to be used with a luer system.
SAFETY Blood Collection Set with Luer Adapter	Individually wrapped and sterile with Luer Adapter (for use with e.g. Standard Tube Holder).
SAFETY Blood Collection Set with Luer Adapter + Holder	Individually wrapped and sterile ready to be used for blood collection.
SAFETY Blood Collection Set with HOLDEX®	

The SAFETY Blood Collection/Infusion Set does not contain any components made of dry natural rubber and is non-DEHP. Accessories containing latex will be marked as such on the packaging.

Procedure

1. Remove SAFETY Blood Collection/Infusion Set from packaging.
2. Check to make sure that the hub is securely locked in place. NOTE: If individual packaging has been opened or tampered with, please choose another needle.
3. Select site for venipuncture. Apply tourniquet and prepare site with appropriate antiseptic. DO NOT PALPATE site after cleansing.

For Blood Collection

1. Select appropriate tube(s) and SAFETY Blood Collection/Infusion Set and, if necessary, connect it to the desired collection system.
2. Carefully remove needle cap from safety-winged needle.
3. Perform venipuncture with patient's arm in downward position. Flashback will confirm successful venipuncture.
4. Immobilize the winged needle with tape when necessary.
5. Collect blood.
6. After completion place gauze over collection site without applying pressure.
7. With one hand, activate the safety mechanism by pressing in the light part on both sides of the hub to engage the lock.
8. Slide the safety mechanism backward until an audible click is heard. The click is a sign that the safety mechanism has been correctly activated.
9. Apply gentle pressure to the puncture site using the gauze pad according to facility protocol.
10. Promptly dispose of SAFETY Blood Collection/Infusion Set in an approved disposal container in accordance with the procedures of your facility.

For short-term IV Infusion

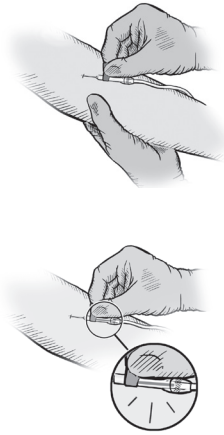
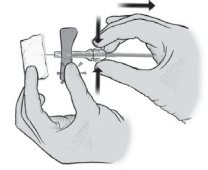
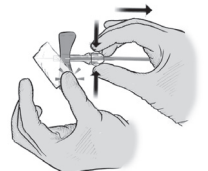
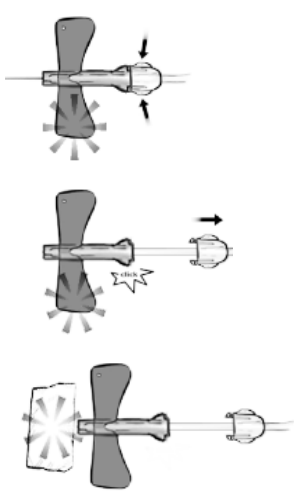
For infusion purposes, aseptically remove any male device (HOLDEX®, Luer Adapter or Luer Adapter + Holder) from the set prior to connection to the female luer port.

Carefully remove needle protective cap from safety-winged needle and prime set in accordance with recommended procedure.

*Maximum Priming Volume (ml)				*Maximum Flow Rate (ml/min)			
Tubing	21G	23G	25G	Tubing	21G	23G	25G
10 cm/ 4 inch	0.27	0.27	-	10 cm/ 4 inch	22.6	9.5	-
19 cm/ 7.5 inch	0.43	0.41	0.41	19 cm/ 7.5 inch	22.8	9.6	5.0
30 cm/ 12 inch	0.56	0.56	0.56	30 cm/ 12 inch	20.8	9.0	5.0

*values established with water

1. Perform venipuncture with patient's arm in downward position and assure that the infusion set is securely attached to the patient.
2. Begin short term IV infusion. NOTE: Please follow your facility's procedures, however, it is recommended that the device be used for single infusion purposes for a maximum of 5 hours.
3. After completion of infusion, hold the gauze down and terminate the procedure (see point 6-10 under blood collection above).

Blood Collection/ Infusion	In Vein Activation of Safety Mechanism	
	When the blood collection/ infusion has been completed, it is recommended to activate the safety mechanism while the SAFETY Blood Collection/Infusion Set is still in the patient's vein.	
	<p>1 Place gauze over site and hold wing down with a thumb or finger. Activate the safety mechanism by pressing in both sides of the hub with one hand to release the lock. Pull the hub backwards.</p>  <p>Example 1</p>  <p>Example 2</p>	<p>2 An audible click is heard when the safety mechanism has been correctly activated. The needle will be completely retracted into the body of the device. Apply pressure to the site until bleeding stops. Verify that the safety mechanism is securely locked.</p> 
	<p>3 Dispose in sharps container.</p>	

Precautions/Cautions

- The device will perform as intended when the instructions are followed accordingly.
- Refrain from carelessly releasing the lock, or forcefully pulling the wing, as such actions may damage the integrity of the device
- Examine individual package for integrity prior to use. If packaging has been damaged, do not use.
- Any used needle is considered contaminated. Discard all used sets together with the holder in biohazard containers approved for their disposal.
- Do not forcefully release or re-activate the safety mechanism after it has been activated.
- Keep hands behind needle at all times during use and disposal.
- Do not bend the needle.
- Do not use for subcutaneous infusion or injection.
- 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.
- A reuse of the product may cause harmful infections, injury or death.
- Gloves should be worn at all times during venipuncture to minimize exposure hazard.
- Avoid blood leakage and any air in the tubing during infusion procedure.
- Special care has to be taken when used on pregnant or nursing women and children.
- Caution must be taken when collecting blood samples from immobilized, haemophilic or epileptic patients, for example.
- Due to the risk of surface contamination from residual blood that may be on the needle tip, it is recommended to dispose of the needle with the tip directed upwards.
- Never cover the safety mechanism with adhesive tape.
- Make sure all air is removed by priming prior to use as short-term IV infusion device.
- Please use each device for either blood collection or infusion but not for both.

Storage of SAFETY Blood Collection/Infusion Sets before use

Store the SAFETY Blood Collection/Infusion Set at 4–36°C (40–96.8°F).

NOTE: Avoid exposure to direct sunlight. Exceeding the maximum recommended storage temperature may lead to impairment of the SAFETY Blood Collection/Infusion Set quality.

Label information:



Item number



Symbol for "single use only"

Literature:



Lot number: Batch number



Temperature Limits



Expiry Date: Product can be used until the end of the month indicated



Manufacturer

CLSI (Clinical and Laboratory Standards Institute)
GP41-A6 Procedures for the Collection of Diagnostic
Blood Specimens by Venipuncture; Approved
Standard-Sixth Edition



Symbol for "sterilisation with ethylene oxide gas"

