

Intended Use

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

Product Description

The 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 Blood Collection/Infusion Set is individually wrapped, sterile and can be used with a luer system (e.g. HOLDEX®). This device 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.

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

Procedure

1. Remove Blood Collection/Infusion Set from packaging.
2. Check the equipment. If individual packaging has been opened or tampered with, please choose another needle.
3. Select site for venipuncture. Apply tourniquet if necessary and prepare site with appropriate antiseptic. DO NOT PALPATE site after cleansing.

For Blood Collection

1. Select appropriate tube(s) and Blood Collection/Infusion Set.
2. Carefully remove needle cap from 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 hold the gauze down.
7. Remove the needle carefully from the vein
8. Maintain pressure on the puncture site according to facility protocol.
9. Promptly dispose of Blood Collection/Infusion Set in an approved disposal container in accordance with the procedures of your facility.

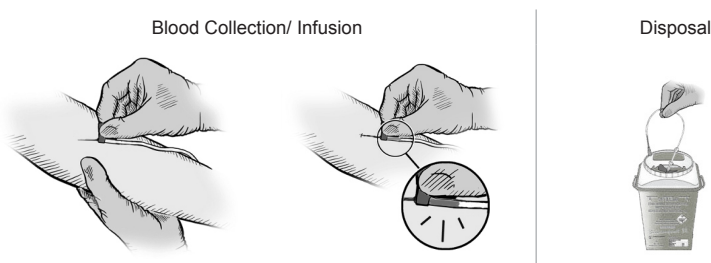
For short-term IV Infusion

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

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

Priming Volume		
Gauges	Tubing	Max. Volume
21G, 23G, 25G	10 cm/ 4 inch	0,26 ml
21G, 23G, 25G	19 cm/ 7.5 inch	0,40 ml
21G, 23G, 25G	30 cm/ 12 inch	0,56 ml

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 6-9 under blood collection above).



Precautions/Cautions








- The device will perform as intended when the instructions are followed accordingly.
- Examine individual package for integrity of packaging prior to use. If packaging has been torn, do not use.
- Any used needle is considered contaminated and should be disposed of in an approved "sharps" biohazard container immediately after use.
- Keep hands behind needle at all times during use and disposal.
- Do not bend the needle.
- Do not use subcutaneously.
- 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, 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 Blood Collection/Infusion 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.
- Avoid blood leakage and any air in the tubing during infusion procedure.
- The plasticizer DEHP is present in the fluid pathway of the Blood Collection/Infusion Set tubing. Leaching of DEHP is possible on contact with lipids. Special care has to be taken when used on pregnant or nursing women and children.
- Caution must be taken when collecting blood samples from immobilised, haemophiliac 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.
- Make sure all air is removed by priming prior to use as short-term IV infusion device.

Storage of Blood Collection/Infusion Sets before use

Store the 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 Blood Collection/Infusion Set quality.

Label information:

	Item number		Symbol for "single use only"
	Lot number: Batch number		Temperature Limit
	Expiry Date: Product can be used until the end of the month indicated		Manufacturer
	Symbol for "sterilisation with ethylene oxide gas"		

Literature:

CLSI (Clinical and Laboratory Standards Institute)
H3-A6 Procedures for the Collection of Diagnostic
Blood Specimens by Venipuncture; Approved
Standard-Sixth Edition

