

Blood Collection/Infusion Set Instructions for use

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. |

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.
- Do not use Blood Collection/Infusion Sets after their expiration date.
- 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. 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.
- 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.
- 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 immobilized, 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.
- IV infusion procedures should be done according to the policies and procedures of your facility.
- Make sure all air is removed by priming prior to use as short-term IV infusion device.
- Each Blood Collection/Infusion Set can be used for either blood collection or infusion, but not for both applications.

Storage

Store the Blood Collection/Infusion Set 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 Blood Collection/Infusion Set quality.

Handling

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 according to your facility's procedure. Remove Tourniquet as soon as blood appears in the tube. Always hold in place by pressing the tube with the thumb to prevent kick-back and to ensure complete vacuum draw. **NOTE:** The first tube in the series will be under-filled due to the dead volume of the flexible tubing. A discard tube (no-additive) is recommended to be drawn prior to ensure the proper anticoagulant to blood ratio.
6. After completion place gauze on collection site without applying pressure.

7. Remove the needle carefully from the vein.
8. Apply gentle pressure on the puncture site using the gauze pad 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. Make sure that there is no air in the system during infusion.

| 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, terminate the procedure (see point 6-9 in the section for blood collection above).










Blood Collection/Infusion



Disposal



Label information

| | | | |
|---|---------------------|---|---------------------------------|
|  | 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: U.S. 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.

Production location:
Nipro (Thailand) Corporation Ltd.
10/2 Moo 8 Bangnomko, Sena,
Phra Nakhon Si Ayutthaya 13110
Thailand
Made in Thailand
Distributed by Greiner Bio-One GmbH, Austria



Greiner Bio-One GmbH
Bad Haller Str. 32
4550 Kremsmünster
Austria

www.gbo.com/preanalytics
office@at.gbo.com
Phone +43 7583 6791