VACUETTE®

greiner BIO-ONE

CE 0123

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SAFETY Blood Collection/Infusion Set
Instructions for use

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.

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

Precautions/Cautions

- The device will perform as intended when the instructions are followed accordingly.
- If the sterile packaging is damaged or unintentionally opened before use, the product must not be used and must be disposed of.
- Do not use SAFETY Blood Collection/Infusion Sets after their expiration date.
- 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/Infusion Sets. Recapping of needles increases the risk of needlestick injury and harmful infections.
- 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. 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 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.
- Do not reuse. 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.
- 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.
- 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.
- Please use each device for either blood collection or infusion but not for both.

Only applicable for member states of the European Union: Should any serious incidents occur in relation to the product, these must be reported to the manufacturer and the competent authority in the member state, in which the user/patient is established.

Storage of SAFETY Blood Collection/Infusion set before use

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

Handling

1. Remove SAFETY Blood Collection/Infusion Set from packaging.
2. Check to make sure that the wing protector is securely locked into its safety mechanism. ***NOTE****: If individual packaging has been opened or tampered with, please choose another device.*

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 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, gently 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

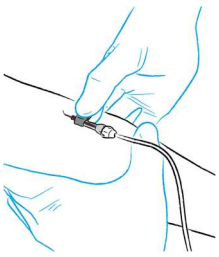
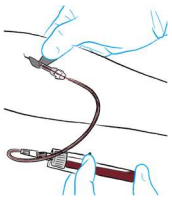
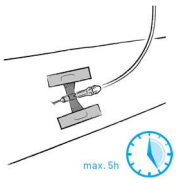
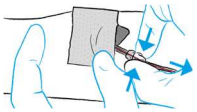
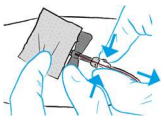
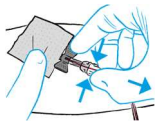
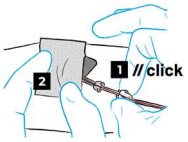
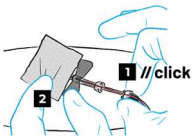
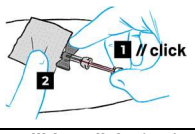
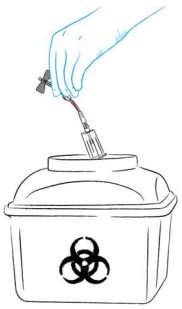
For infusion purposes, aseptically remove any male device (Luer Adapter or Luer Adapter + Holder) from the set prior to connection to the female luer port.
Carefully remove needle protective cap from safety-winged needle and prime set in accordance with recommended procedure. Make sure that there is no air in the system during infusion.

***Maximum Priming Volume** (ml)			
Tubing	**21G**	**23G**	**25G**
10 cm / 4 inch	0.3	0.3	-
19 cm / 7.5 inch	0.4	0.4	0.4
30 cm / 12 inch	0.6	0.6	0.6

***Maximum Flow Rate** (ml/min)			
Tubing	**21G**	**23G**	**25G**
10 cm / 4 inch	20.8	9.6	-
19 cm / 7.5 inch	20.4	9.4	5.5
30 cm / 12 inch	20.8	9.6	5.2

* 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, terminate the procedure (see point 6-10 under blood collection above).

Venipuncture	Blood Collection OR Infusion	In Vein Activation of Safety Mechanism		Disposal
		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.		Dispose in sharps container.
1 	**2a**  **2b** 	**3a**  **3b**  **3c** 	**4a**  **4b**  **4c** 	**5** 
		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.**	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.	

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Label information

	Manufacturer		Temperature limit	MD	Medical device
	Use-by date		Do not re-use		Do not use if package is damaged and consult instructions for use
LOT	Batch code	STERILE EO	Sterilized using ethylene oxide		Keep away from sunlight
REF	Catalogue number		Consult instructions for use	CH REP	Authorized representative in Switzerland
	Date of manufacture		Single sterile barrier system	Rx Only (USA)	Prescription device

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,
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CH REP

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