



Instructions for Use Safety Blood Collection Set / Infusion Set for Single Use

INDICATIONS FOR USE:

The RELI® SAFETY BLOOD COLLECTION SET / INFUSION SET FOR SINGLE USE is a single-use, sterile, winged venipuncture needle bonded to flexible tubing with or without a luer adapter and/or tube holder. The RELI® SAFETY BLOOD COLLECTION SET / INFUSION SET FOR SINGLE USE is used for blood collection and/or the short-term infusion of intravenous fluids (up to 2 hours under direct clinical supervision). The venipuncture needle is designed to be covered with a safety mechanism, which can be activated to cover needle immediately following venipuncture to aid in the protection against accidental needlestick injury.

PRODUCT DESCRIPTION:

The RELI® Safety Blood Collection Set / Infusion Set for Single Use is a single-use, sterile, winged blood collection needle bonded to flexible tubing with or without a luer adapter and/or tube holder. The RELI® Safety Blood Collection Device / Infusion Set for Single Use is individually wrapped, sterile, non-pyrogenic and is designed for collection of blood specimens or short-term intravenous administration of fluid (up to 2 hours under direct clinical supervision). When it's equipped with male luer adapter and/ or tube holder, it can be used for taking samples from the patient through vacuum tubes. It is also indicated for short-term intravenous fluids (up to 2 hours under direct clinical supervision) after attaching to an IV set, a transfusion set or to other compatible/appropriate device.

Model	Product Name	Description
GSBC-T	RELI® Safety Blood Collection Set with Tube Holder	Individually wrapped and sterile ready to be used for blood collection.
GSBC	RELI® Safety Blood Collection Set / Infusion Set	Individually wrapped and sterile with Luer adapter (for use with Standard Tube Holder).
GSIS	RELI® Safety Infusion Set	Individually wrapped and sterile allowing set to be used with a luer system.

3", 7", 12" Tubing lengths

OPERATION PROCEDURE:

Preparation

Note: Venipuncture should be performed wearing gloves.

1. Peel apart package and remove the safety blood collection set / infusion set. Check to make sure that the slide locker is securely placed in its original position.
2. Select site for venipuncture. Apply tourniquet and prepare site with appropriate antiseptic.

For Blood Collection

Note: Should be performed wearing gloves.

• Make sure that the safety mechanism is not hindered when taping the set in place.

1. Carefully remove plastic sleeve from needle, connect with luer adapter and thread the luer adapter into Holder when needed.
2. Perform venipuncture with patient's arm in downward position. Flashback will confirm successful venipuncture.
3. Immobilize the wings with tape when necessary.
4. Collect blood.
5. After completion hold the gauze down.

6. Withdraw the needle from the vein and activate the safety mechanism using one of the two techniques listed below:

Option A: With one hand use middle finger to cover the puncture site with a gauze pad and place the index finger on the curved design to anchor, with the other hand withdraw the wings or tubing back to activate the safety mechanism until hearing 2 audible clicks, indicating the needle is fully locked as photo-4, protected and ready for disposal.

Option B: Use one hand to cover the puncture site with a gauze pad, with the other hand, place the index finger on the curved design to anchor, withdraw wings or tubing by the thumb finger and middle finger to activate the safety mechanism until hearing 2 audible clicks, indicating the needle is fully locked as photo-4, protected and ready for disposal.

7. Maintain pressure with the gauze pad on the puncture site according to facility protocol.

8. Promptly dispose of safety blood collection set in an approved disposal container in accordance with the procedures of your facility.

For short-term IV Infusion (up to 2 hours under direct clinical supervision)

Note: Should be performed wearing gloves.

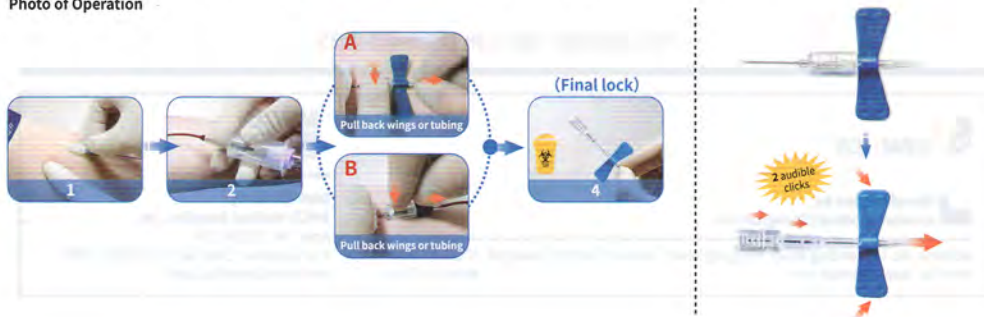
• When securing the device in place, make sure the safety mechanism is not hindered.

• Prime set if necessary in accordance with your facility's procedure.

• Infusion priming volume is listed on the device labeling as the letter "V". For example, GSIS21G-7, 21G x 3/4" x 7" (0.8 x 20mm x 19cm) set, V=0.52ml.

1. For infusion purposes, aseptically remove the Luer Adapter or Luer Adapter+ Holder from the RELI® Safety Blood Collection Set / Infusion Set or Safety Blood Collection Set with Tube Holder prior to connection to the female luer port.
2. Carefully remove needle protective cap from safety-winged needle and prime set in accordance with recommended procedure.
3. Perform venipuncture with patient's arm in downward position and assure that the infusion set is securely attached to the patient.
4. 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 2 hours.
5. After completion of infusion, hold the gauze down and terminate the procedure (see point 6-8 under blood collection above).

Photo of Operation



Precautions/Cautions:

- The device will perform as intended when the instructions are followed accordingly.
- Refrain from carelessly releasing the lock, or forcefully pulling the retractable cartridge, as such actions may damage the integrity of the device
- Examine individual package for integrity of packaging prior to use. If the packaging is broken or fragments are found in the packaging, do not use.
- Do not forcefully re-activate or tamper with 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 subcutaneously.
- The product should be used by trained clinical staff for venous blood sampling or infusion and must comply with relevant operation guidelines and requirements of related laws, regulations, and policies and procedures of your facility.
- Ethylene oxide sterilization is valid for three years, refer to the single packaging for Lot Number and Sterilization Expiration Date. If the validity period of sterilization has expired, do not use the device.
- Please check the product before use, if the plastic sleeve of the venipuncture needle is off, do not use the device.
- Any used needle is considered contaminated and should be disposed of in an approved "sharps" biohazard container immediately after use.
- 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.
- Discard all used Safety Blood Collection Set with the Holder together 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.
- 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, hemophilic or epileptic patients.
- 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.
- Do not tape over or hinder the safety mechanism when securing the set in place.

Storage of the RELI® Safety Blood Collection Set / Infusion Set for Single Use

NOTE: Avoid Exposure to direct sunlight. Exceeding the maximum recommended storage temperature may damage the integrity of the device.

Storage: The packaged product should be stored in a cool, dry, ventilated and noncorrosive area, and be kept away from disinfection products which contain fluorine.













Shelf Life: 3 years

Transportation: Avoid exposing the device or packaging to direct sunlight. Keep dry. Avoid exposure to rain and snow or excess humidity where the package or device may get wet.

After-sale Service: MYCO Medical Supplies, Inc.

Version No: GT0020-IFU-MYCO-4-20190920-A1

Symbols:

Symbol	Explanation	Symbol	Explanation
	Do not re-use		Keep dry
	Keep away from sunlight		Consult instructions for use
	Do not use if package is damaged		Sterilized using Ethylene Oxide
	Does not contain Phthalates		Batch Code
	Not made with natural rubber latex		Manufacturer
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a physician.		Catalog Number
 EXP	Expiry Date		

For Customer Care Call 1-919-460-2535



Manufactured by:
Gentier Medical (Shanghai) Inc.

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