

Template	Instructions for Use for Top & Bottom Blood Bag (without Inline Filter)	Size	210×297mm
Drawing No.	TH-TZ-226	Material	Ordinary wood pulp paper
Version	02/2020	Color	Black
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Approved by	Lu Jianqiang	Effective date	February 20, 2020
Note			



INSTRUCTIONS FOR USE FOR TOP&BOTTOM BLOOD BAG



APPLICABLE PRODUCTS

OTA-450SSTB

DESCRIPTION

1. For collection, processing and storage of human blood and blood components.
2. The product is sterile and nonpyrogenic after terminal steam sterilization.

PRE-COLLECTION BLOOD BAG PREPARATION

1. Open the transparent overwrap at the tear notches and take out the blood bag system.
2. Before venipuncture, inspect the blood bag system for visual defects, confirm that there is no turbidity or leakage of anticoagulant or additive solution, confirm that the needle cap has never been opened. **Note:** Avoid mistakenly lock the needle into the needle protective device before blood collection.
3. Place the blood bag on a scale of blood mixer (or blood collection machine) as far as possible below the donor's arm.
4. Close the clamp (Figure 1, #2) on sampling tubing.
*Or close the donation tubing, if there is no Pre-donation Sampling Device (PDS) in the system or no breakaway cannula on the donation tubing.

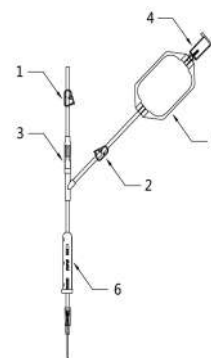


Figure 1

COLLECTION

1. Apply tourniquet or blood pressure cuff to donor's arm. Disinfect the venipuncture site according to institutional SOP.
2. Hold the needle cap and the hub with both hands and twist to break the tamper-proof between the needle hub and the cap. Remove the needle cap straight so that the needlepoint does not come in contact inside the needle cap.
3. Perform venipuncture. Note that the marked point is upward to ensure that the edge of the needle tip is upward.
4. Open the clamp (Figure 1, #2) or breakaway cannula on the sampling tubing and collect required volume of blood into the in-line sampling pouch (Figure 1, #5).
*If there is no sampling pouch in the system, directly insert the vacuum tube into the tube holder (Figure 1, #4) for blood sampling.
5. Close the clamp (Figure 1, #2) on the sampling tubing.
6. Open the breakaway cannula (Figure 1, #3) or the clamp on the donation tubing. **Note:** Make sure that the breakaway cannula is fully opened.
7. Immediately on starting the collection, mix blood with anticoagulant solution thoroughly and continue until completion of blood collection.
8. Collect the required quantity of blood within the limits indicated on the primary bag label.
9. Close the clamp (Figure 1, #1) on the donation tubing after completion of blood collection.
10. Remove the tourniquet or blood pressure cuff, then remove the needle and lock the needle in the Needle Protective Device (NPD) (Figure 1, #6) completely. Connect the NPD to the barrel of the vacuum tube holder (Figure 1, #4). Seal and cut off the donation tubing just above the Y-connector, discard the needle and any other devices according to local protocol.
11. Strip the blood from the donation tubing into the primary bag, mix thoroughly and allow the tube to fill again, repeat several times, then seal and cut the donation tubing as needed.
12. Blood collection is expected to be completed within 12 minutes. **Note:** If it exceeds 15 minutes, the collected blood may not be suitable for the preparation of platelets and cryoprecipitates.
13. Blood should be stored at 20 to 24 °C and should not be refrigerated. Platelets should be prepared within 24 hours after blood collection.

USING OF PRE-DONATION SAMPLING DEVICE

Complete the following operations during blood collection:

1. Pre-donation sampling device with sampling pouch (Figure 1, #5)
 - 1.1 Open the cap of the tube holder, insert vacuum tube to collect the required number of blood samples. **Note:** Before collecting the blood samples, keep the sampling pouch positioned vertically so that air is at the upper end to prevent air being mixed into the vacuum tube.
 - 1.2 During blood sampling, hold the tube holder and vacuum tube firmly to prevent the sampling needle from slipping out of the vacuum tube, to ensure that the required blood samples are collected.
2. Pre-donation sampling device without sampling pouch
 - 2.1 According to the number of blood samples to be collected, insert the vacuum tube into the tube holder in sequence to collect blood samples.

COMPONENT SEPARATION

Top&Bottom bag system: (intended for preparation of platelets, buffy coat removed red cells and plasma, by buffy coat method)

1. Load the whole system on the centrifuge bucket, ensure that the breakaway cannula is placed at the upper position. **Note:** Proper position can prevent the blood bag from bursting during centrifugation.
2. Centrifuge the whole system at 22°C according to local validated standard procedures.
3. After centrifugation, load the whole system on the blood component separator. Clamp the tubing to platelet storage bag.
4. Use the blood component separator in accordance with the operation manual.
5. First break the breakaway cannula (Figure 2) on the primary bag and then break the breakaway cannula on the SAG-Mannitol solution bag.



Figure 2

6. Blood component separator transfers plasma upward to plasma bag and red cells downward to SAG-M bag, remain buffy coat in the primary bag. If single unit platelet concentrate is to be prepared: remain appropriate plasma in the primary bag to get a buffy coat suspension.
7. After separation, seal transfer tubings of plasma bag and red cell suspension bag and detach the blood components.
8. Strip the red cell from the transfer tubing into the bag, mix thoroughly and allow the tube to fill again, repeat two times, to ensure that there is red cell in the tubing. **Note:** For identification purposes, the coding segment closest to the bag is usually remained with the bag.
9. Rest the prepared buffy coat suspension for more than 1 hour, prepare pooling platelet concentrates according to local validated standard procedures by using a pooling set.
10. If the system (which with platelet storage bag) is used for single unit platelet preparation
 - 10.1 Close the tubing near the breakaway cannula of the primary bag, mix thoroughly the contained buffy coat and appropriate plasma, rest the bag for more than 1 hour.
 - 10.2 Centrifuge the primary bag and platelet bag at 22°C according to local validated standard procedures.
 - 10.3 Transfer platelet into platelet storage bag by the blood component separator. **Note:** Platelets should be separated immediately after centrifugation.
11. If the system is used for cryoprecipitate preparation
 - 11.1 Place the fresh frozen plasma under condition of 2 to 6°C overnight for unfreezing.
 - 11.2 After unfreezing, perform heavy centrifugation at 2 to 6°C. Transfer the upper layer cryoprecipitate-depleted plasma to the empty transfer bag, remained is the cryoprecipitate.
 - 11.3 Cryoprecipitate can also be prepared by Quick Unfreezing – Siphonage Method.
 - 11.4 The prepared cryoprecipitate should be frozen immediately.

BLOOD COMPONENTS STORAGE

Store the blood components according to appropriate regulations.

PRECAUTIONS

1. Store the blood bag with closed outer package and/or individual package in a cool and dry place after products removal from shipping carton.
2. Do not use the blood bags if the outer package is opened more than 15 days.
3. Use the blood bag within the same day of opening individual package.
4. Use blood bag in accordance with the instructions for use.
5. Do not use unless solutions are clear.
6. Do not use if the bag shows visible signs of damage.
7. Protect the bags and tubings from sharp objects.
8. Do not use if the needle cap shows signs of opening.
9. Do not use if fluid path closures are loose or not intact.
10. Do not vent.
11. When frozen, plastic is more fragile.
12. Do not add medicine to blood.
13. Check blood bags and blood components for defects before blood transfusion.
14. Use transfusion set compatible with ISO EN 1135-4.
15. The blood bag is for single use. No secondary use. Discard the used blood bag into the medical waste bin.

SPECIAL PRECAUTION: This product contains di (2-ethylhexyl) phthalate (DEHP). Based on animal experimental data, there is a risk of adverse effects on reproduction and development in a specific patient group, and long-term exposure to DEHP should be avoided. These specific patients are male neonates, infants, children, adolescent boys, and women who are pregnant or breastfeeding. However, in cases where the benefits of DEHP-containing products are more important than any health risks, medical procedures should not be avoided. Please refer to the existing literature to make a favorable choice.



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