

Template	Instructions for Use for WB Filter Blood Bag	Size	210×297mm
Drawing No.	TH-TZ-099	Material	Ordinary wood pulp paper
Version	02/2020	Color	Black
Designed by	Lu Yangge	Reviewed by	Wu Yun Wangxiaoqing
Approved by	Lu Jianqiang	Effective date	February 20, 2020
Note			



INSTRUCTIONS FOR USE FOR WB FILTER BLOOD BAG



APPLICABLE PRODUCTS

OTC-450SSFW

DESCRIPTION

•Intended for the collection of human blood, the filtration of whole blood and the preservation of blood components.

VENEPUNCTURE

- A
 - 1) Tear open the transparent overwrap.
 - 2) Place blood pack at a distance of ~50cm below donor arm, ideally on an automated blood mixer.
 - 3) Apply tourniquet.
 - 4) Thoroughly disinfect site of venepuncture.
- B
 - 5) To remove the needle cap: Hold the hub and twist the cap. Remove the cap in a straight line to avoid any damage to the needle tip.
 - 6) Carry out venepuncture.

PRE-DONATION SAMPLING

- C
 - 1) Allow the sampling pouch to fill.
 - 2) While filling the sampling pouch, do not let the sampling pouch hang freely. Fill the sampling pouch.
 - 3) Close the clamp (b) and break the breakaway cannula (c) on the donation line with a side to side motion.
- D
 - 4) Immediately on starting the collection, thoroughly mix the blood/anticoagulant and continually mix throughout the collection.
 - 5) Release the cap of the vacuum tube holder by pushing the handle of the cap with a thumb. Invert the sampling pouch to ensure any air is directed to the bottom of the sampling pouch.
 - 6) Collect the blood samples using the vacuum tube holder and the appropriate sampling tubes.

BLOOD COLLECTION

- 1) Ensure that the anticoagulant and the blood are mixed thoroughly immediately upon the start of collection, and also at least every 50mL during the donation, ideally using an automated blood mixer.
- 2) Collect the quantity of blood stated on the pack label.
- 3) Once the required quantity has been reached, close the clamp of the donation line (a) and seal the donation tubing, using a permanent closure device, between the blood pack and the Y-junction of any attached devices.
- 4) Release the tourniquet, and immediately mix the full blood pack.
- 5) If using an in-line filter, do not strip the donation tubing. Seal it close to the pack (~2cm), using a permanent closure device.
- 6) If required (quality control, crossmatch, pool of buffy coats...), strip the donation line, and mix the pack. Repeat several times. Seal and cut the donation tubing as needed.

USE OF NEEDLE PROTECTIVE DEVICE

- E
 - 1) After donation and sampling, move the needle protective device close to the hub of the needle.
 - 2) Remove the donation needle, then gently lower the needle into the barrel of the needle protective device until a click is heard.
 - 3) The needle and needle protective device must be held upright. Ensure that no pressure is put on the donation line at any time, to prevent possible spillage.
 - 4) The needle protective device may be pushed into the barrel of the vacuum tube holder.
 - 5) The needle, needle protective device and any other devices should be disposed of in a safe manner.

PACK HANDLING WHILST PROCESSING

- F
 - 1) After filtration, centrifuge all transfer packs together as required by the blood transfusion center, and then do the separation.
 - 2) Process the pack as required by the blood transfusion center. Ensure the bags and tubing are correctly packed for centrifugation.
 - 3) To allow fluid transfer, break the cannula at the seal, by bending the breakaway cannula with a side to side motion.
 - 4) After transfer, seal the transfer tubing, using a permanent closure device, and cut to separate.

*Note:

- 1) If time interval between whole blood collection and separation is over 4 hours, the leukoreduced whole blood shall be placed at 4±2°C.
- 2) Centrifugation at 4±2°C.
- 3) After separation, red cell shall be stored at 4±2°C as soon as possible.

HANDLING OF FILTER

- 1) Hang the whole blood unit. Position the empty transfer bag below the filter and make sure the head height is 120 to 150cm.
- 2) Clamp the bypass and the tubing below filter.
- 3) Break the breakaway cannula on the collection pack.
- G** 4) Open the clamp below filter, keep the bypass closed, whole blood will start to flow into the filter. Leave the unit to gravity prime, filter and drain.
- 5) When flow stops, close clamp below filter, and open the bypass, transfer air through bypass into upper collection bag, close the bypass after air exhausted.
- 6) Seal the tubing close to the filter. If required (quality control, crossmatch...), strip the tube, and mix the pack. Repeat several times. Seal and cut the tubing as needed.
- 7) Discard the filter and the upper collection bag according local procedure in appropriate medical waste containers.
- 8) Obtain the leukoreduced whole blood in the transfer bag.
- *Caution:
 - 1) Do not squeeze, tap or hit the filter or the packs during filtration
 - 2) Do not centrifuge the filter together with blood pack.
 - 3) Do not manhandle the filter(s).
 - 4) If either face of the filter remains white, the blood components have not been leukoreduced and must be discarded.
- *Suggestion:
 - 1) Time interval between collection and filtration shall be 2 to 20 hours when whole blood stored at 4±2°C. Before filtration, whole blood shall be placed in room temperature (18 to 25°C) for 0.5 to 1 hour.
 - 2) Time interval between collection and filtration shall be 2 to 12 hours when whole blood stored at 10-25°C.
 - 3) Filtration shall be conducted at room temperature (18°C to 25°C).

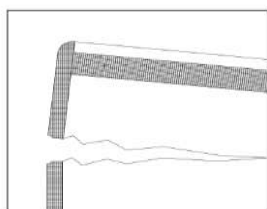
HANDLING OF PORT PROTECTORS

- H** 1) Peel off the port protector.
- 2) Hold down the port protector pieces with one hand.
- I** 3) Using the free hand, take the spike and engage into the port.
- 4) Twist the spike to secure fully in port.

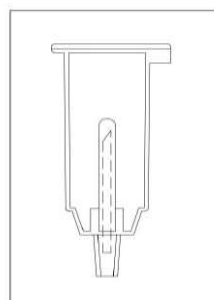
PRECAUTIONS

1. After products removal from the carton, store the blood bag with closed outer package and/or individual package in a cool and dry place.
2. Do not use the blood bags if the outer package is opened more than 15 days.
3. Use the blood bag on 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 medication 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.

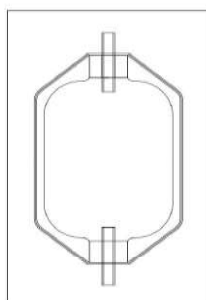
SPECIAL PRECAUTION: This product contains di (2-ethylhexyl) phthalate (DEHP). Based on animal experimental data, there is a risk of adverse effects on reproduction and development in a specific patient group, and long-term exposure to DEHP should be avoided. These specific patients are male neonates, 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.



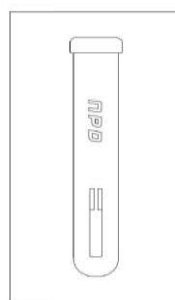
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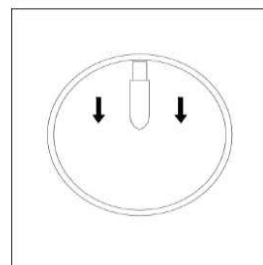
Vacuum tube holder



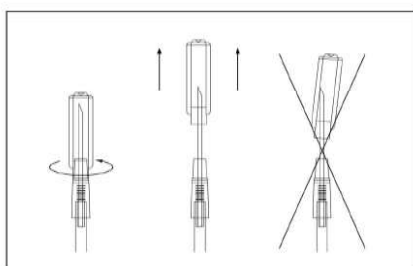
Sampling pouch



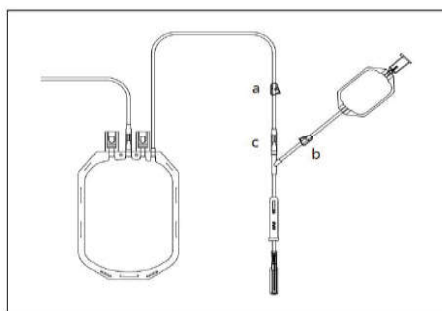
Needle protective device



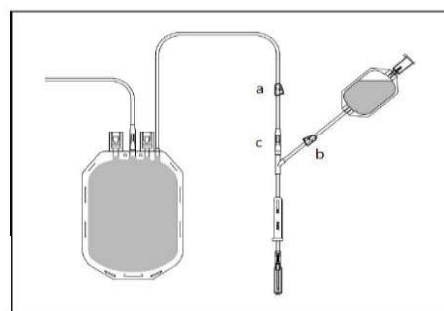
Whole blood filter



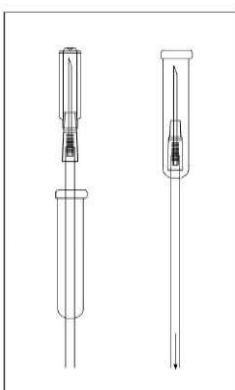
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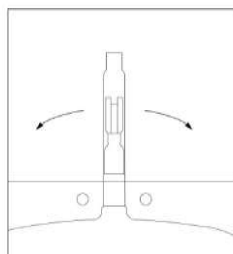
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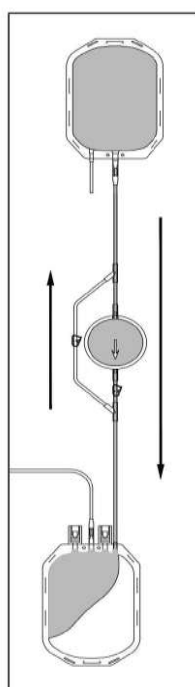
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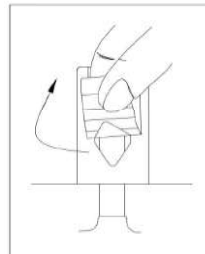
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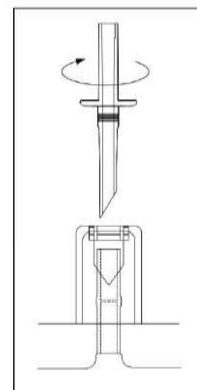
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