RAVIMED

INSTRUCTIONS FOR USE

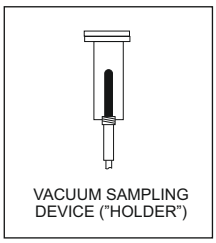
CONTAINERS FOR BLOOD COLLECTION, STORAGE AND PREPARATION WITH PRESERVATIVE SOLUTIONS

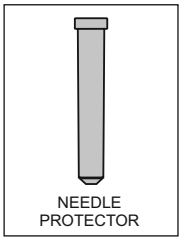
Appropriation of the product:

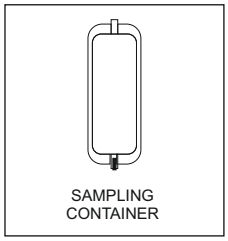
The blood bag set is appropriated for collection, delivery, storage and preparation of blood

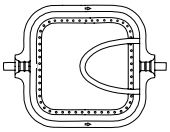
CAUTION:

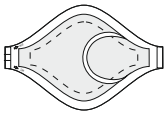
1. **Only qualified medical personnel equipped with protective means (gloves etc.) may use the product.**
2. Remove the bags from the individual packaging directly before use.
3. Do not use unless solution is clear.
4. Do not use in case of leakage.
5. Do not use if individual packaging is damaged.
6. Used blood bags or those which exceeded prescribed time limit, must be utilized according to regulations for medical materials after contact with blood.


VACUUM SAMPLING DEVICE ("HOLDER")


NEEDLE PROTECTOR


SAMPLING CONTAINER


LEUKOCYTE REDUCTION FILTER FOR WHOLE BLOOD


LEUKOCYTE REDUCTION FILTER FOR ERYTHROCYTES

BLOOD COLLECTION

1. Check tightness of blood bag and individual packaging. Untight or damaged must be rejected. SOLUTION MUST BE CLEAR.
2. If the set includes leukocyte reduction filter for whole blood, close the red clamp Ⓓ first (Fig.5.).
3. Put the bag on a scale below donor's arm or monitor quantity of taken blood in another way.
4. Apply blood pressure cuff, make vein visible and disinfect puncture site.
5. Close the donor tube with clamp Ⓐ near the three-way connector.
6. Break the valve (Fig.1.). Clamp Ⓑ must not close the tube leading off to sampling container.
7. Remove the needle cover (Fig.2.): twist the cover (c) in opposite direction to the handle (h). I**MPORTANT: Ultrathin needle wall. Bring the needle out with care in order not to damage needle blade**. Puncture the vein, release blood pressure cuff and start blood collection.
8. First collect approx. 30 mL of blood to the sampling container. Close clamp Ⓑ on the tube leading off to the sampling container and release clamp Ⓐ on donor tube leading off to mother container.
9. Collect blood to the mother container up to the quantity shown on the label.
10. As soon as blood collection starts, mix gently blood with anticoagulant solution.
11. Collect blood samples for tests from the sampling container using vacuum sampling tube. Close the lid of the sampling device (Fig.3).
12. After collection of blood withdraw the needle and secure puncture site.
13. After withdrawal of the needle from the vein, hide it inside the protector (Fig.4), by pulling the tube until the needle locks inside it.
14. Once more mix blood gently with anticoagulant solution (invert blood up and down at least 3 times).
15. Squeeze out blood from the donor tube into the bag using roller clamp and mix. Allow blod mixed with anticoagulant to flow back into the tubing.
16. Once more check tightness of blood bag. Check the numbers of test samples.
17. Seal the donor tubing with aluminium rings or previously adjusted HF heat sealer.
18. Store containers with blood at proper temperature until blood preparation is made.

CAUTION: If the set includes leukocyte reduction filter for whole blood, proceed blood filtration.

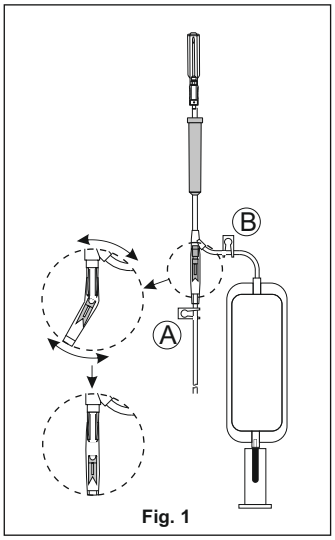


Fig. 1

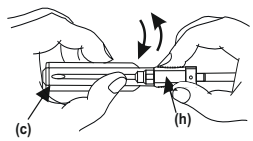


Fig. 2

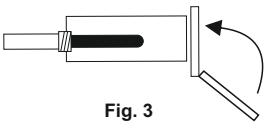


Fig. 3

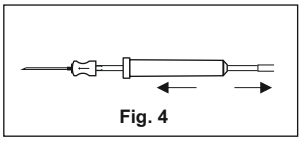


Fig. 4

INSTRUCTIONS FOR BLOOD FILTRATION

CAUTION:

To provide optimal filtrating conditions be sure the collected blood is at temperature between +20ºC and +24ºC. This temperature range may be obtained by storing blood at room temperature for 2 hours.

a) Filtrate blood through the leukocyte filter for whole blood after its collection and after bringing it to a temperature between +20ºC and +24ºC or **b)** Store collected blood overnight at temperature between +2ºC and +6ºC, thereafter on the next day bring it to a temperature between +20ºC and +24ºC and filtrate through the leukocyte filter for whole blood.

1. Close the clamps: Ⓒ and Ⓓ (Fig.5.).
2. Lay horizontally the container into which blood is to be filtered. Place the container with blood high enough so that the filter hangs down freely vertically underneath. Break the valve at the container with blood (Fig.6.), squeeze the container and open the red clamp Ⓓ . Continue squeezing until the filter is completely filled with blood.
3. Hang the container with blood over the container for filtered blood so high as the tubing allows and let blood flow freely through the filter. Do not let blood flow through the by-pass.
4. When the filtration is over close the white clamp Ⓒ . In order to let air escape from the container with filtered blood open the red clamp Ⓓ , put the container into vertical position, squeeze air out of it and finally, before releasing the squeeze, close the red clamp Ⓓ .
5. To make full use of the collected blood open the white clamp Ⓒ and empty the filter with the help of air from the container.
6. Seal the tubing between the filter and the container with filtered blood.

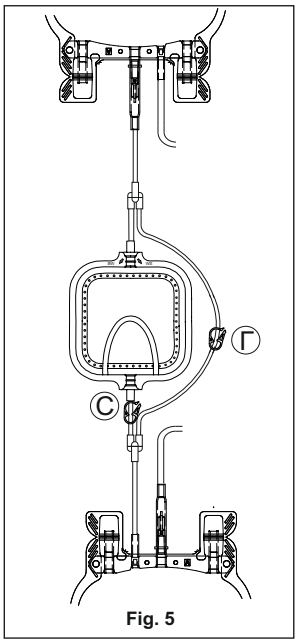


Fig. 5

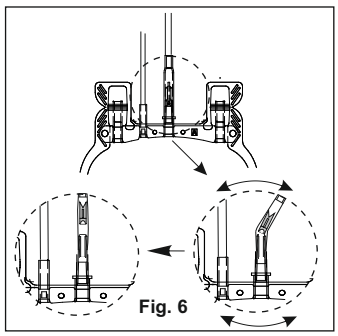


Fig. 6

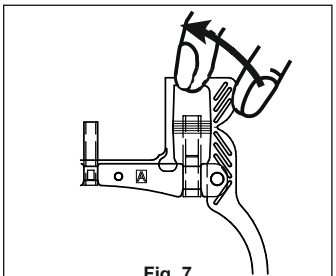


Fig. 7

PREPARATION OF WHOLE BLOOD

1. **Blood preparation must be made only by qualified staff in accordance to the configuration of the set of containers and in compliance with the accepted regulations**.
2. Insert the containers carefully in vertical position into the centrifuge rotor container. The material used for balancing must be dry, DO NOT EXCEED ACCELERATON **5000 x g**.
3. If the set includes a platelet container, proceed the preparation at temperature between +20ºC and +24ºC, in other case - at temperature +4ºC.
4. If the set includes a leukocyte reduction filter for erythrocytes, proceed filtration of separated red cells.

FILTRATION OF SEPARATED RED CELLS

CAUTION:

To provide optimal filtrating conditions be sure the separated red cells are at temperature between +20ºC and +24ºC. This temperature range may be obtained by storing the separated red cells at room temperature for 2 hours.

a) Filtrate red cells through the leukocyte filter for erythrocytes after their separation and bringing them to a temperature between +20ºC and +24ºC or **b)** Store separated red cells ovenight at temperature between +2ºC and +6ºC, thereafter on the next day bring them to a temperature between +20ºC and +24ºC and filtrate through the leukocyte filter for erythrocytes. **c)** Transfer SAGM solution through the filter in order to wet the filter before red cells filtration.

1. Break the valve at the container with SAGM solution (Fig.6).
2. Squeeze the SAGM solution through the filter into the main container with CPD anticoagulant and red cells (Fig.8a.) and mix the contents carefully.
3. Squeeze the mixed contents of the main container through the filter for erythrocytes back into the emptied SAGM container (Fig.8b.).

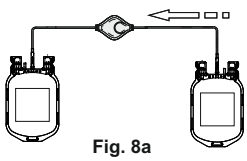


Fig. 8a

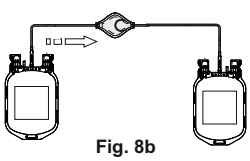


Fig. 8b

MD STERILE PHT DEHP 10℃ 30℃ CE 2274

ADDITIONAL REMARKS
1. Store containers filled with blood at temperature between +2°C and +6°C.
2. Crossmatch before transfusion.
3. Do not add any medication to blood.
4. Mix blood thoroughly before transfusion.
5. Remove outlet protection (Fig.7.) and connect transfusion set with filter.
6. Do not vent.

INSTRUCTION FOR STORAGE OF CONTAINERS
1. Store not used containers at temperature between +10°C and +30°C in clean, dry (humidity<65%) accomodations with access of fresh air.
2. Blood bags should be stored in original cardboard boxes.
3. Do not store blood bags directly on the floor. Usage of palettes under cardboard boxes is recommended
4. Keep away from direct sunlight.

ADDITIONAL INFORMATION
Preservative solutions ensure blood anticoagulation and storage for:

anticoagulant 4% sodium citrate in 0,9% sodium chloride	- 48 hours
anticoagulants CPD and ACD(A)	- 21 days
anticoagulant CPDA-1	- 35 days
additive solution SAGM	- 42 days

CAUTION:
Any serious incident that has occured in relation to the device shall be reported to the manufacturer and to the competent authority of the Member State in which the user / patient is established.

Explanation of graphical symbols used on labels and instructions leaflets

MD — Medical Device
date of manufacture
manufacturer
use-by date
LOT — batch code
REF — catalogue number

consult instructions for use
do not re-use
do not use if package is damaged
PHT DEHP — contains or presence of phthalates
STERILE — sterilized by steam; sterile fluid path
non-pyrogenic fluid path

leukocyte filtration
30°C / 10°C — temperature limit
anticoagulant solution
additive solution
whole blood container

red blood cell container
plasma container
platelets container
processing container

CE 2274 — the product complies with requirements of European Medical Devices Directive MDD 93/42/EWG
the manufacturer is certified by Notified Body No. 2274

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