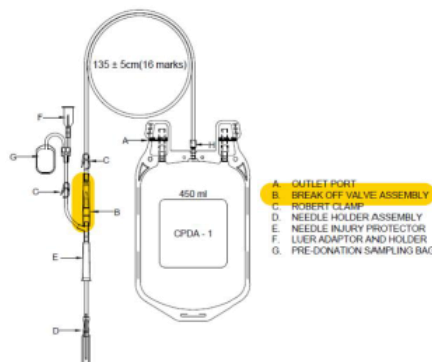


TERUMO BLOOD BAG with Pre-Donation Sampling Bag on Sampling Arm, with or without pre-attached Holder and Needle Injury Protector.

In addition, our blood bags now have a new feature called **CLIKTIP® frangible connector**, an easy breakaway valve that makes an audible click when broken. The valve has a large inner diameter to support smooth extraction and fast transfer of components or additive solution. This feature helps reduce the loss of blood components during separation and avoid mixing of low-layer components.



Please refer to our 'Instructions for Use', below for more information.

- Intended for the collection and the preservation of human blood.
- For single use only. Sterile and non-pyrogenic fluid path. Sterilized by steam.

PRECAUTIONS

- This product contains phthalates (DEHP). Patient groups that include pregnant or nursing women and children are considered to be the most at risk to potential harmful effects of exposure to DEHP. However, regulatory bodies have noted that the benefit of doing a needed procedure is far greater than the risk associated with exposure to DEHP. It is the responsibility of the treating physician to balance this risk the patient.
- Once the aluminium dispenser package is opened, keep the unopened individual packs inside the dispenser package by folding and securing the open-end package with a clip.
- Use the individual packs within 15 days.
- Do not use if the packaging or product has been damaged or soiled.
- Do not use unless the solution(s) is (are) clear.
- Avoid excessive heat and direct sunlight. Protect from freezing.
- Recommended storage conditions; temperature range 2°C to 35°C.
- The blood bag configuration is specified on the aluminium foil pack label.
- Read these instructions carefully before use.
- When using the Needle Injury Protector which is fitted to the 'Y', please read the paragraph 'Using Needle Injury Protector' before proceeding.

INSTRUCTIONS FOR THE BLOOD COLLECTION

CAUTION Use an aseptic technique. Do not vent.

1. For purposes of identification, check that the numbered tubes of each blood bag bear the full sequence of numbers.
2. Make a loose knot in the donor tube between the bag and the clamp.

3. Close all clamps.
4. Place the collection bag as far as possible below donors arm.
5. Apply a blood pressure cuff. Disinfect the puncture site.
6. Remove the needle protector by twisting it off and perform the venipuncture.

CAUTION Do not touch the needle while and after removing its protector.

7. Using an appropriate technique, attach the donor tube to donor's arm.

A. In case of blood sampling arm with or without holder pre-attached; proceed as follows:

8. Open the clamp (A) to allow the primary bag to fill.
9. During the donation, mix the blood and the anticoagulant at regular intervals.
10. Collect the recommended quantity of blood as specified on the label of the primary bag. (Conversion of blood weight to volume: see Table 1.)
11. At the end of the donation:
 - Close the clamp and tighten the knot firmly.
 - Seal and sever the tube between the knot and the clamp.
12. Immediately after the blood collection, invert the bag several times to mix the blood thoroughly with the anticoagulant. Transfer the blood contained in the tube to the bag by means of a hand stripper. Mix thoroughly and allow the tube to fill again with blood. Make an appropriate number of seals for segment necessary for the tests.

CAUTION Begin sealing at the tube end and work towards the bag.

B. In case of pre-donation sampling bag, proceed as follows (see Fig. 3):

8. Open the clamp (B) on the blood sampling arm to allow the blood to flow to the pre-donation sampling bag. Fill the sampling bag with the desired volume.
9. Close the clamp (B) on the blood sampling arm and break the CLIKTIP on the donor tube to START the collection. Ensure the blood is mixed immediately and at regular intervals with anticoagulant during the collection.

TO COLLECT THE BLOOD SAMPLES

CAUTION Proceed with the collection of the blood samples in the evacuated blood collection tubes as soon as possible to prevent blood to clot in the pre-donation sampling bag.

- i. Open the cap of the Tube Holders
- ii. Maintain the pre-donation sampling bag upside down to ensure the air is maintained at the opposite side of the outlet and insert the plastic or glass blood collection tubes firmly into the Tube Holder (Fig.3).
- iii. After filling, remove the tube from the Holder. Repeat the process to take other samples.

TO COLLECT THE BLOOD SAMPLES:

In case of pre-attached holder, go to point 15.

Equipment required:

Glass or Plastic evacuated blood collection tubes.

13. Insert the Luer Adapter into the Holder (Fig.1).
14. Remove the cap and connect the male luer of the Luer Adapter to the female luer at the end of the blood sampling arm (Fig.2).
15. Open the cap of the Tube Holder. Break the CLKTIP of the blood sampling arm twice to allow the blood to flow.
16. Insert the blood collection tube firmly into the Holder.
17. After filling, remove the tube from the Holder. Repeat the process to take other samples.
18. Re-clamp the donor tube, remove the blood pressure cuff then remove the needle from the donor's arm, in case of Needle Injury Protector, read the paragraph "Using Needle Injury Protector".

CAUTION For safety, destroy and dispose the needle using an appropriate method.

19. Return the unit to the component laboratory for processing the blood according to local protocols.

10. Collect the recommended quantity of blood as specified on the label of the primary bag. (Conversion of blood weight to volume: see Table 1.)
11. At the end of the donation close the clamp (A) on the donor tube and tighten the knot firmly. Seal and sever the tube between the knot and the clamp (A).
12. Remove the blood pressure cuff, then remove the needle from the donor's arm, in of Needle Injury Protector, read the paragraph 'Using Needle Injury Protector'.

CAUTION For safety, destroy and dispose of the needle using an appropriate method.

13. Immediately after the blood collection, invert the bag several times to mix the blood thoroughly with the anticoagulant.
14. Transfer the blood contained in the tube of the bag by means of a hand stripper. Mix thoroughly and allow the tube to fill again with blood. Make an appropriate number of seals necessary for the tests.

CAUTION Begin sealing at the tube end and work towards the bag.

15. Return the unit to the component laboratory for processing the blood according to local protocols.

USING NEEDLE INJURY PROTECTOR

1. Remove the blood pressure cuff, then slide the Needle Injury Protector towards the needle as close as possible.
2. Remove the needle from the donor's arm while holding the Needle Injury Protector (NIP) by the hand and immediately slide and cover the needle with the NIP by pulling the 'Y' gently until the needle is surely locked with the NIP (Fig.4).
3. LOCK the NIP in the Tube Holder by inserting the NIP in the Holder (Fig.5).

CAUTION For safety, destroy and dispose of the NIP/Holder using an appropriate method.

PRECAUTIONS FOR OXYGEN ABSORBER

- The sachet contained in the aluminium foil pack absorbs oxygen and generates heat on contact with air. It should be handled with caution.
- Discard the oxygen absorber sachet without opening it.
- Dispose of the aluminium foil pack with the oxygen absorber sachet in it.
- Do not dispose of together with waste containing volatile or flammable material.

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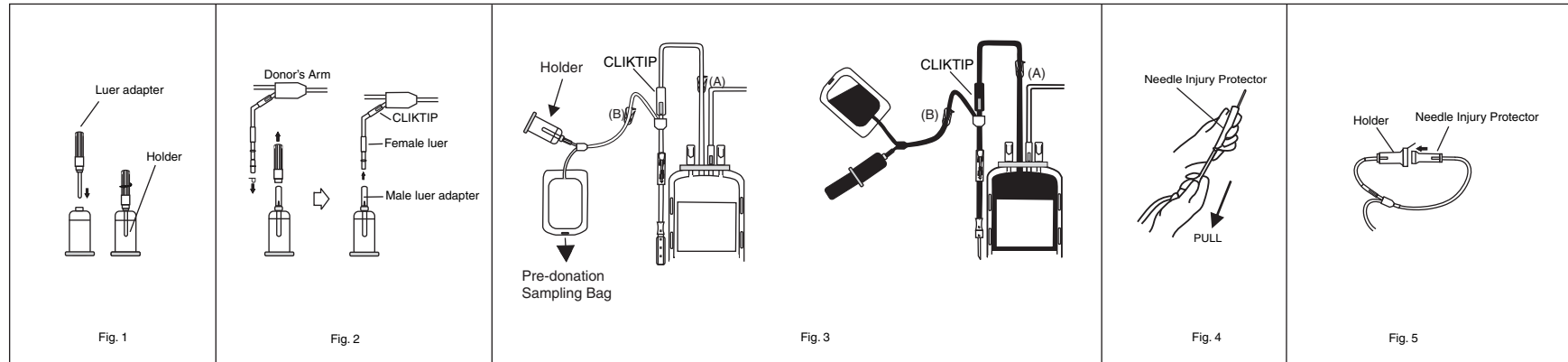


Table 1. CONVERSION OF BLOOD WEIGHT TO VOLUME

Volume	250 mL	300 mL	350 mL	400 mL	430 mL	450 mL	500 mL
Weight	263 g	315 g	368 g	420 g	452 g	473 g	525 g

	Manufactured Date		Units
	Manufactured By		For single use only.
	Code No.		Non-pyrogenic Fluid path
	Lot No.		Do not use if the package is damaged
	Expiry Date		Do not use if the product, its sterile barrier system or its packaging is damaged or shows any sign of deterioration
	Sterile fluid path, sterilized by steam.		Read the instructions for use.
	Contains Phthalates: Bis (2-ethylhexyl) Phthalate (DEHP)		Do not vent

IFU Code : 10201XUB

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