

PB-1CD456U0Y

1. Intended use

PB-1CD456U0Y is a single blood bag, which contain 63ml CPDA-1 anticoagulant solution and is intended for the collection, storage and transfusion of 450ml human blood. This blood bag system has following safety features: Needle injury protector, Sampling arm and Pre-donation sampling bag.

2. Packaging

The blood bags are packed in a primary package made of Polypropylene and then in a secondary package of Aluminum foil. These Aluminum foils are then packed in a shipping carton.

Product code	Qty of bags / Aluminum foil	Qty of Aluminum foils / Carton	Qty of bags / Carton
PB-1CD456U0Y	8 units	5 units	40 units

3. Technical Specifications

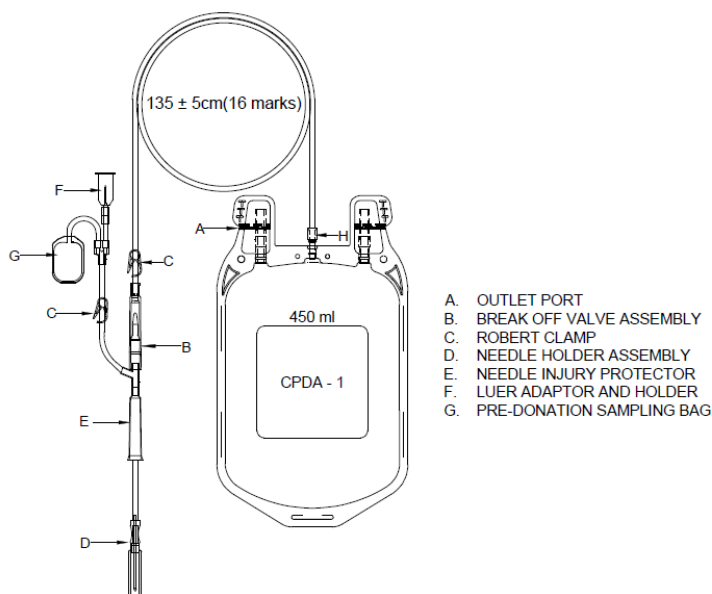
Specifications

Material	:	PVC (DEHP)
Inner diameter of the tube	:	2.95 ± 0.05 mm
Outer diameter of the tube	:	4.4 ± 0.1 mm
Donor tube length	:	135 ± 5cm (16 marks)
Phlebotomy needle	:	16 gauge needle





Bag dimensions

Bag Type	Volume (ml)	Inside Width (mm)	Outside Width (mm)	Inside Length (mm)	Outside Length (mm)
Primary bag	450ml	120 ± 3	132 ± 3	180 ± 5	204 ± 5

Drawing



Primary label

TERUMO BLOOD BAG CPDA-1		CE 1639
For collection of human blood: 450 mL	Donor Number	
Contains 63 mL of anticoagulant CPDA-1 solution. 100mL of CPDA-1 solution contains:	ABO Blood Group	
Citric Acid (monohydrate) USP : 0.327 g		
Sodium Citrate (dihydrate) USP : 2.630 g		
Monobasic Sodium Phosphate (dihydrate) USP : 0.251 g	Rh Type	
Dextrose (anhydrous) USP : 2.900 g		
Adenine USP : 0.0275 g		
Water for Injection USP q.s. : 100mL	Do not infuse after	
CAUTIONS :	Serology : Non-reactive to	
<ul style="list-style-type: none"> ● Store blood at 4°C ± 2°C. ● Cross-match before transfusion. ● Identify recipient as partner to cross-match. ● Do not add medication. ● Mix blood thoroughly immediately before use. ● Infusion set must have a filter. ● Do not use unless the solution is clear. 		
		
 TERUMO PENPOL Private Limited, Puliyaakonam, Thiruvananthapuram, India-695 573 Mfg.Lic.No. MFG/MD/2019/000170		
EC REP	TERUMO BCT EUROPE N.V., Ikaroslaan 41, 1930 Zaventem, BELGIUM	LABEL : 1310045XEB
REF		
LOT		

Secondary Packing Label


TERUMO
SINGLE BLOOD BAG CPDA-1

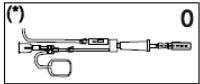
FOR COLLECTION OF HUMAN BLOOD: 450 mL

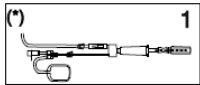
CE
1639

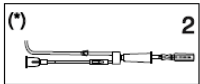
CPDA-1 63 mL
100 mL of CPDA-1 Solution contains :

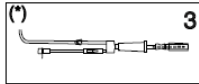
Citric Acid (monohydrate) USP	: 0.327 g
Sodium citrate (dihydrate) USP	: 2.630 g
Monobasic Sodium Phosphate (dihydrate) USP	: 0.251 g
Dextrose (anhydrous) USP	: 2.900 g
Adenine USP	: 0.0275 g
Water for Injection USP qs.	: 100mL

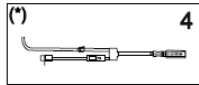
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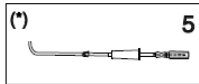
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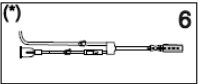
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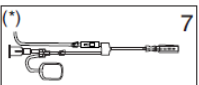
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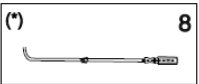
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Precaution : **DONOR NEEDLE : 16 G x 38 mm**


- ⌋ For single use only. Sterile and non-pyrogenic fluid path.
- Do not use unless the solution is clear.
- Do not use if the packaging or product has been damaged or soiled.
- ⌋ Read the instructions carefully before use.
- ⌋ Store at temperature 2°C to 35°C.
- ⌋ Avoid excessive heat and direct sunlight. Protect from freezing.
- ⌋ Use the blood bags as soon as possible, within 15 days after opening the aluminium foilpack.
















LOT :

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
REF :

LABEL: 1511458YXUA

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UNITS

 **TERUMO PENPOL Private Limited**
Puliyarakonam, Thiruvananthapuram, India-695 573
Mfg.Lic.No. MFG/MD/2019/000170

 **TERUMO BCT EUROPE N.V.**, Ikaroslaan 41, 1930 Zaventem, BELGIUM

AU Sponsor
Terumo BCT Australia Pty Limited
Suite 4.02
15 Orion Rd
Lane Cove, NSW, 2066
Australia

Box label

TERUMO	CE
SINGLE BLOOD BAG CPDA-1	1639
FOR COLLECTION OF HUMAN BLOOD : 450mL	
LOT :	
 :	
 :	
REF :	
 :	
<hr/>	
 TERUMO PENPOL Private Limited PULIYARAKONAM, THIRUVANANTHAPURAM, INDIA-695 573 Mfg.Lic.No. MFG/MD/2019/000170	AU Sponsor Terumo BCT Australia Pty Limited Suite 4.02 15 Orion Rd Lane Cove, NSW, 2066 Australia
EC REP TERUMO BCT EUROPE N.V. , Ikaroslaan 41, 1930 Zaventem, BELGIUM	
LABEL: 181100XUB	

IFU

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

- 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 for 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 of the 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 primary bag at least 60 cm below the arm of the donor.
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 the 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.
 - i. Close the clamp and tighten the knot firmly.
 - i. 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 the 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 Holder.
- 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 CLIKTIP 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 protocol.

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 case 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 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 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 protocol.

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.

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

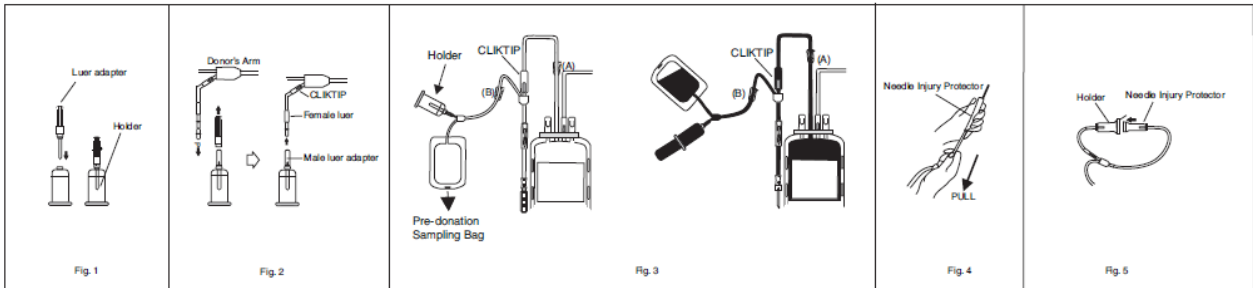


Table 1. CONVERSION OF BLOOD WEIGHT TO VOLUME

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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