PB-1CD456M0Y

1. Intended use

PB-1CD456M0Y 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, Holder 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 Aluminium foil. These Aluminium foils are then packed in a shipping carton.

Product code	Qty of bags / Aluminum foil	Qty of Aluminium foils / Carton	Qty of bags / Carton
PB-1CD456M0Y	8 units	5 units	40 units

3. Technical Specifications

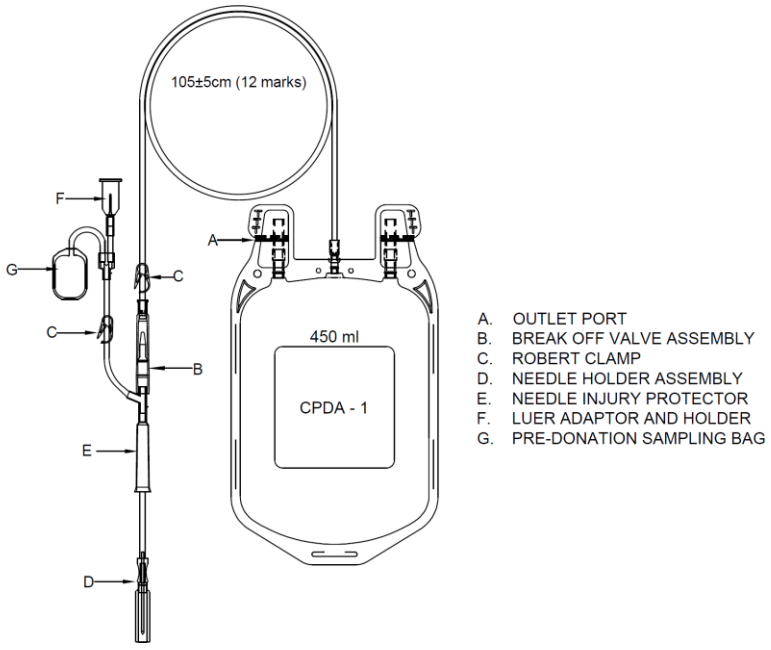
Specifications

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	:	105 ± 5cm (12 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



Primay Label

Secondary Packing Label

TERUMO

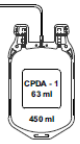
CE 1639

CPDA-1 BLOOD BAG / SACCHE PER SANGUE / BOLSA DE SANGRE / SACO DE SANGUE / ΑΣΚΟΣ ΑΙΜΑΤΟΣ / POCHE A SANG

FOR COLLECTION OF HUMAN BLOOD / PER LA RACCOLTA DI SANGUE INTERO / PARA LA EXTRACCION DE SANGRE HUMANA / PARA RECOLHA DE SANGUE HUMANO / ΓΙΑ ΤΗ ΣΥΛΛΟΓΗ / POUR PRELEVEMENT DE SANG HUMAIN : 450 mL

- CPDA-1 - 63 mL
  100 mL - CPDA-1
  Acidum citricum (monohydr.) 0.327 g,
  Natrii citras (dihydr.) 2.630 g,
  Mononatrii phosphas (dihydr.) 0.251 g,
  Dextrosum (anhydr.) 2.900 g,
  Adenine 0.0275 g, Aqua ad iniectabilia q.s. 100 mL

(*)



(*) 0 (*) 3 (*) 6

(*) 1 (*) 4 (*) 7

(*) 2 (*) 5 (*) 8

Use the blood bags as soon as possible, within 15 days after opening the aluminium foil pack. / Utilizzare le sacche appena possible, e comunque entro 15 giorni dall'apertura dell'involucro. / Usar las bolsas en los 15 días posteriores a la apertura del envasado de aluminio / Utilizar os sacos nos 15 dias posteriores à abertura de embalagem de aluminio / Χρησιμοποιήστε τους ασκούς το συντομότερο δυνατόν και εντός 15 ημερών από την ημέρα ανοίγματος της συσκευασίας αλουμινίου / Utiliser les poches dès que possible, au plus tard dans les 15 jours après l'ouverture de l'emballage d'aluminium.

Donor needle / Ago per donatore / Calibre aguja / Calibre da agulha / Βελόνα δότη / Aiguille à prélèvement : 16 G x 1½" (1.60 x 38 mm)

STERILE

PHT DEHP

LOT :

: **8 UNITS / UNITÀ / UNIDADES / UNITES / ΜΟΝΑΔΕΣ**

:

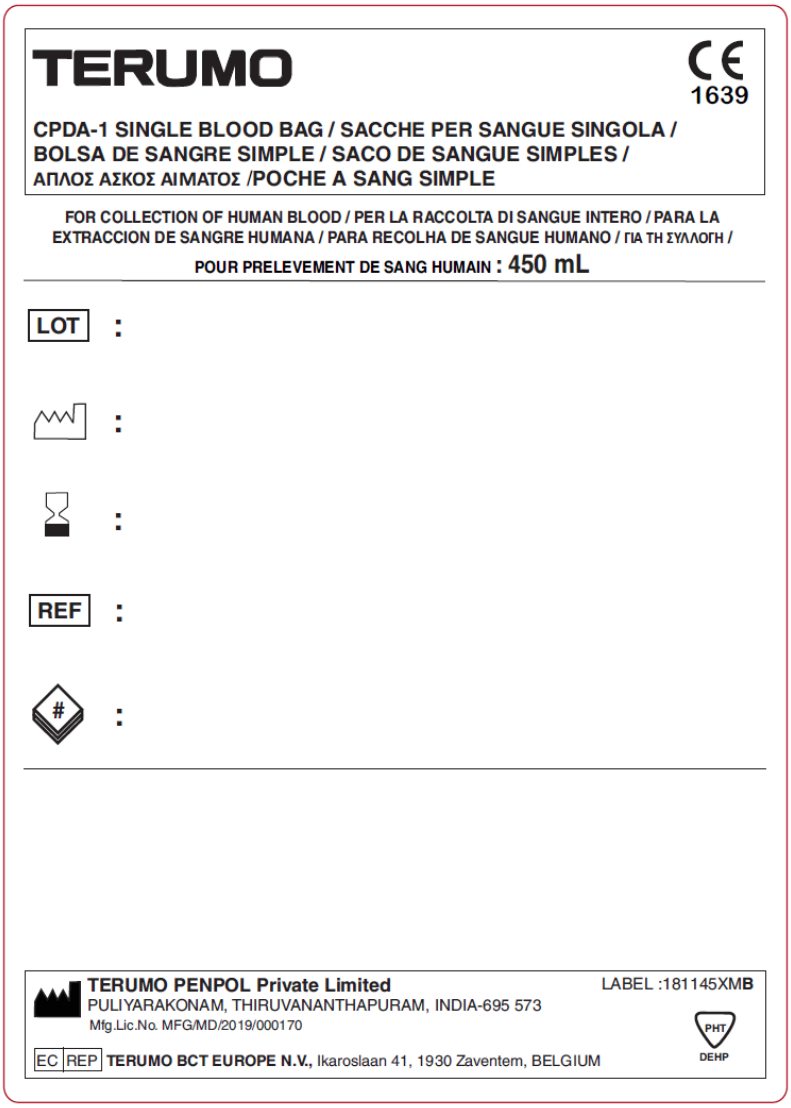
REF :

TERUMO PENPOL Private Limited
PULIYARAKONAM, THIRUVANANTHAPURAM, INDIA-695 573
Mfg.Lic.No. MFG/MD/2019/000170

LABEL : 1511458YXMA

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

Box Label


TERUMO
CE
1639
CPDA-1 SINGLE BLOOD BAG / SACCHE PER SANGUE SINGOLA /
BOLSA DE SANGRE SIMPLE / SACO DE SANGUE SIMPLES /
ΑΠΛΟΣ ΑΣΚΟΣ ΑΙΜΑΤΟΣ /POCHE A SANG SIMPLE
FOR COLLECTION OF HUMAN BLOOD / PER LA RACCOLTA DI SANGUE INTERO / PARA LA
EXTRACCION DE SANGRE HUMANA / PARA RECOLHA DE SANGUE HUMANO / ΓΙΑ ΤΗ ΣΥΛΛΟΓΗ /
POUR PRELEVEMENT DE SANG HUMAIN : 450 mL
LOT :
:
:
REF :
:
TERUMO PENPOL Private Limited
PULIYARAKONAM, THIRUVANANTHAPURAM, INDIA-695 573
Mfg.Lic.No. MFG/MD/2019/000170
LABEL :181145XMB
PHT
DEHP
EC REP TERUMO BCT EUROPE N.V., Ikaroslaan 41, 1930 Zaventem, BELGIUM

IFU

TERUMO

CE 1639

Blood Bag with blood sampling arm or pre-donation sampling bag

ENGLISH

- Intended for the collection and the processing of human blood, and the preservation of blood components.
- Sterilized by steam. Sterile in an unopened and undamaged unit package.
- Sterile and non-pyrogenic fluid path.

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.
- For single use only. Do not reuse. Do not resterilize. Do not reprocess. Reprocessing may compromise the sterility, biocompatability and functional integrity of the device.
- Do not use if the packaging or product has been damaged or soiled.
- Once the aluminium foil pack is opened, keep the unopened individual packs inside the foil pack by folding and securing the open-end of the package with a clip (Fig. 6).
- Use the individual packs within 15 days after opening the aluminium foil pack.
- 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 a pre-donation sampling bag, be sure clamp (A) on the donor tube is closed before performing the venipuncture.
- 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:	**B: In case of pre-donation sampling bag, proceed as follows (see Fig. 3):**
8. Open the clamp 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 necessary for the tests. CAUTION Begin sealing at the tube end and work towards the bag. TO COLLECT THE BLOOD SAMPLES: In case of pre-attached holder, go to point 15.	8. Open the clamp (B) on the sampling arm to allow the blood flow to the pre-donation sampling bag. After filling the sampling bag with the desired volume, close the clamp (B) on the sampling tube. 9. Break the CLIKTIP on the donor tube twice and open the clamp(A) 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 evacuated blood collection tubes as soon as possible to prevent blood to clot in the pre-donation sampling bag. i. If present, remove 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).

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

Equipment required :
Glass or plastic evacuated blood collection tubes.

13. Insert the Luer Adapter into the glass or plastic evacuated blood collection tubes. (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. If present, remove 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 the local protocols.

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

iii. After filling, remove the tube from the Holder. Repeat the process to take other samples.

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 the 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 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).

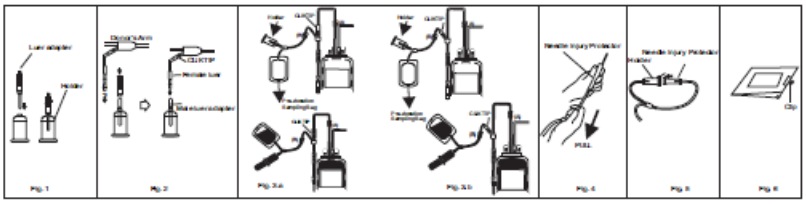
CAUTION For safety, destroy and dispose of the NIP/Holder using an appropriate method.

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.

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



	Non-pyrogenic fluid path
	Do not use if the product, its sterile barrier system or its packaging is damaged or shows any sign of deterioration
	Do not use if package is damaged
	Do not vent
PHT DEHP	Contains phthalates: Bis (2-ethylhexyl) phthalate (DEHP)
#	Contents