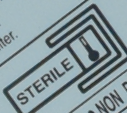


TERUMO PENPOL® BLOOD BAG CPD 450mL

Anticoagulant Citrate Phosphate Dextrose Solution IP 65mL
for the collection and preservation of 450mL human blood.
Each 100 mL CPD contains:

Citric acid monohydrate IP	0.327 g
Sodium citrate dihydrate IP	2.630 g
Sodium dihydrogen phosphate dihydrate IP	0.251 g
Dextrose anhydrous equivalent to Dextrose monohydrate IP	2.550 g
Water for injection IP	100 mL

Caution
Do not use if there is any visible sign of damage or deterioration to the bag or solution.
Mix blood and anticoagulant at several intervals during collection.
Store blood between 2° C and 8° C.
Cross-match before transfusion.
Transfusion set must have a filter.



DO NOT VENT • STERILE FLUID PATH • NON PYROGENIC • SINGLE USE • DO NOT USE IF PACKAGE IS DAMAGED • READ INSTRUCTIONS
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
 / Mfg. Date
 15-07-2021
 YG



Donation Unit No:	Rh group
ABO Blood Group	Date of Expiry
Date of Collection	Collected and Typed by
Serology Non Reactive to:	HBV
Syphilis	Malarial parasite
HIV I & II	

Top and Bottom Blood Bag System With Integral Leukocyte Filter for Red Blood Cells Technical Card



Product Name	Top and Bottom Blood Bag System With Integral Leukocyte Filter for Red Blood Cells
Description	Blood bag system containing citrate phosphate dextrose (CPD) anticoagulant and saline, adenine, glucose-mannitol (SAGM-2) additive solution with an integral leukocyte filter for red blood cells
Manufacturer	Terumo Penpol Private Ltd., Puliyaakonam, Thiruvananthapuram, India, 695 573
EC Representative	Terumo BCT Europe N.V., Ikaroslaan 41, 1930 Zaventem, Belgium
Classification	Class IIb (MDD 93/42/EEC amended by 2007/47/EC)
Sterilization	Steam sterilization
Storage conditions	<ul style="list-style-type: none"> ■ Avoid excessive heat and direct sunlight. Protect from freezing. ■ Store unused sets between 2 °C and 35 °C.
Shelf life	<p>When stored under the specified conditions:</p> <ul style="list-style-type: none"> ■ 24 months in the original unopened aluminum pouch ■ 15 days after opening the original aluminum pouch
Conformities	<ul style="list-style-type: none"> ■ ISO 9001:2015 ■ ISO 13485:2016/EN ISO 13485:2016 ■ ISO 14001:2015 ■ ISO 3836-1:2019 ■ ISO 3826-3:2006

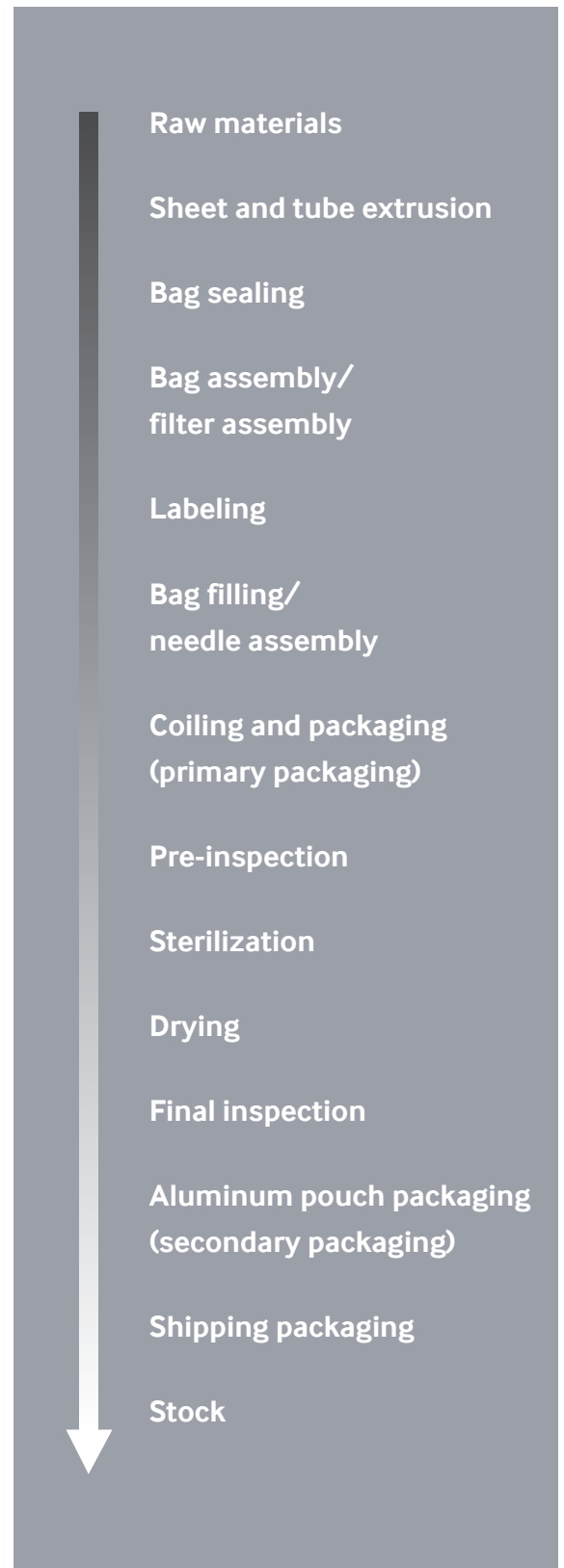
General Features

Filter	<ul style="list-style-type: none"> ■ BioFlex RCC Filter A2BG0130
Plastic	<ul style="list-style-type: none"> ■ Polyvinyl chloride (PVC) with DEHP
Surface	<ul style="list-style-type: none"> ■ Embossed surface
Needle	<ul style="list-style-type: none"> ■ Triple-bevel-cut needle with ultra-thin wall design ■ Sand-blasted and silicon-lubricated cannula surface
Tubes	<ul style="list-style-type: none"> ■ Embossed surface ■ Unique sequence of numbers for identification ■ Compatible with Terumo Blood and Cell Technologies sterile connection devices
CLIKTIP® valve	<ul style="list-style-type: none"> ■ Frangible connector that is opened by a double-bend movement ■ Makes an audible “click” sound when opened ■ Large inner diameter
Mold	<ul style="list-style-type: none"> ■ Bag design with round corners
Outlets	<ul style="list-style-type: none"> ■ Long-neck inner tube ■ Tube dimension and diaphragm position are designed for spikes according to ISO 1135-4
Labels	<ul style="list-style-type: none"> ■ Easy to write on ■ Tamper-evident ■ Single- or double-color graphics ■ Comply with ISBT guidelines ■ Pre-printed with solution contents and bag type
Barcode system	<ul style="list-style-type: none"> ■ ISBT 128 barcodes on bag labels ■ GS1-128 barcodes on secondary packing and shipping carton
Single bag set	<ul style="list-style-type: none"> ■ Blood bags are sterilized in a polyester cast polypropylene over-wrap
Aluminum pouch	<ul style="list-style-type: none"> ■ Airtight aluminum pouch
Quality controls	<ul style="list-style-type: none"> ■ Physical, chemical, and biological tests of materials and final products comply with ISO 3826-1:2019, USP and IP standards

Materials

Component	Material
Bag sheet	Extruded polyvinyl chloride (PVC) (DEHP)
Tubes	Extruded PVC (DEHP)
Needle cannula	Stainless steel
Needle hub	Molded PVC
Needle protector	Inner: Molded PVC Outer: Molded polypropylene (PP)
Needle injury protector (NIP)	Molded PP
Outlet ports	Molded PVC
CLIKTIP valve cover	Molded PVC
CLIKTIP valve body	Molded polycarbonate (PC)
Y connector	Molded PVC
Sampling arm female luer	Molded PC
Sampling arm cap	Synthetic rubber
Sampling needle	PC hub/stainless steel needle/ isoprene sheath
Holder	Molded PP
Pre-donation sampling bag	Extruded PVC
Clamp	Molded polyacetal
Filter housing	Soft shell, PVC (DEHP)
Filter material	Non-woven polyester fiber
Primary packaging (individual wrap foil)	Polyester cast PP
Secondary packaging (aluminum pouch)	Multilayered laminated aluminum foil
Shipping box	Corrugated paper carton

Production Flow (simplified)



Blood Component Storage

Component	Storage Condition
Whole blood storage	CPD up to 21 days at 4 °C ± 2 °C
Red blood cell concentrate	CPD/SAGM- 2 up to 42 days at 4 °C ± 2 °C
Platelet concentrate	5 days at 22 °C ± 2 °C with slow and continuous agitation

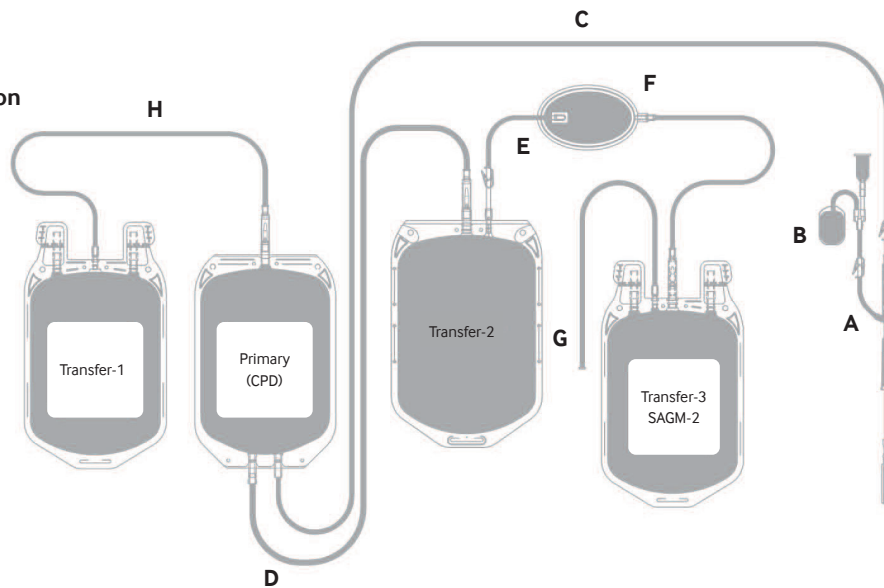
Product Range

Product Code	Configuration	Packaging Quantity	Collection Volume	CPD Volume	SAGM-2 Volume	Transfer Bag 1	Transfer Bag 2	Transfer Bag 3	Transfer Bag 4
PB-4RO456J0Y	Quadruple TAB blood bag with integral filter for red blood cells	6 aluminum pouches containing 3 blood bag sets each	450 mL	63 mL	100 mL	Empty transfer bag suitable for storage of plasma	Empty transfer bag	SAGM-2 transfer bag suitable for storage of red blood cells	—
PB-4RO356J0Y	Quadruple TAB blood bag with integral filter for red blood cells	6 aluminum pouches containing 3 blood bag sets each	350 mL	49 mL	80 mL	Empty transfer bag suitable for storage of plasma	Empty transfer bag	SAGM-2 transfer bag suitable for storage of red blood cells	—
PB-5RO456J0Y	Penta TAB blood bag with integral filter for red blood cells	6 aluminum pouches containing 3 blood bag sets each	450 mL	63 mL	100 mL	Empty transfer bag suitable for storage of plasma	Empty transfer bag suitable for 5-day platelet storage	Empty transfer bag	SAGM-2 transfer bag suitable for storage of red blood cells
PB-5RO356J0Y	Penta TAB blood bag with integral filter for red blood cells	6 aluminum pouches containing 3 blood bag sets each	350 mL	49 mL	80 mL	Empty transfer bag suitable for storage of plasma	Empty transfer bag suitable for 5-day platelet storage	Empty transfer bag	SAGM-2 transfer bag suitable for storage of red blood cells

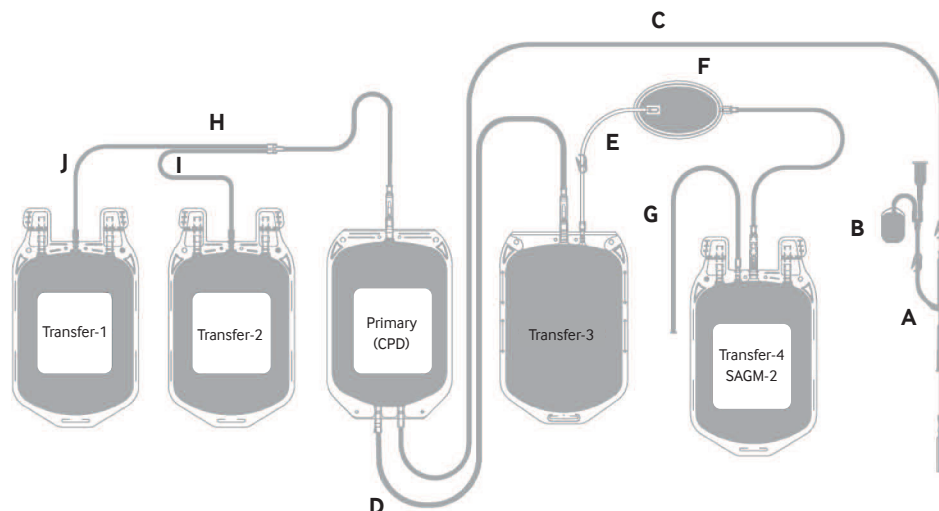
* Top-and-bottom configuration

Blood Bag Configuration

Quadruple Bag Configuration



Penta Bag Configuration



Technical Features

Product Code	Spec	PB- 4RO456J0Y	PB-4RO356J0Y
Bag type	Config	Top-and-bottom processing bag with a leukocyte filter for red blood cells	
Donation volume	mL	450	350
Primary/transfer bags nominal capacity	mL	450/450/450/450	350/350/350/350
Needle size Needle length	Gauge Length	Exposed length 35+2/-0mm	
Primary bag (CPD)	Internal Length	180 mm ± 5 mm	160 mm ± 5 mm
	Internal Width	120 mm ± 3 mm	120 mm ± 3 mm
Transfer bag 1	Internal Height	180 mm ± 5 mm	145 mm ± 5 mm
	Internal Width	120 mm ± 3 mm	120 mm ± 3 mm
Transfer bag 2	Internal Length	180 mm ± 5 mm	145 mm ± 5 mm
	Internal Width	120 mm ± 3 mm	120 mm ± 3 mm
Transfer bag 3 (SAGM-2)	Internal Height	180 mm ± 5 mm	145 mm ± 5 mm
	Internal Width	120 mm ± 3 mm	120 mm ± 3 mm
Product Code	Spec	PB-5RO456J0Y	PB-5RO356J0Y
Bag type	Config	Top-and-bottom processing bag with a leukocyte filter for red blood cells	
Donation volume	mL	450	350
Primary/transfer bags nominal capacity	mL	450/450/450/450/450	350/350/350/350/350
Needle size Needle length	Gauge Length	Exposed length 35+2/-0mm	
Primary bag (CPD)	Internal Length	180 mm ± 5 mm	160 mm ± 5 mm
	Internal Width	120 mm ± 3 mm	120 mm ± 3 mm
Transfer bag 1	Internal Height	180 mm ± 5 mm	145 mm ± 5 mm
	Internal Width	120 mm ± 3 mm	120 mm ± 3 mm
Transfer bag 2	Internal Height	180 mm ± 5 mm	145 mm ± 5 mm
	Internal Width	120 mm ± 3 mm	120 mm ± 3 mm
Transfer bag 3	Internal Length	180 mm ± 5 mm	145 mm ± 5 mm
	Internal Width	120 mm ± 3 mm	120 mm ± 3 mm
Transfer bag 4 (SAGM-2)	Internal Height	180 mm ± 5 mm	145 mm ± 5 mm
	Internal Width	120 mm ± 3 mm	120 mm ± 3 mm
Tubing Specs		PB-4RO456J0Y/PB-4RO356J0Y	PB-5RO456J0Y/PB-5RO356J0Y
Tube section			
A	Length (mm)	250 ± 30	250 ± 30
	No. of tube segments	0	0
B	Length (mm)	210 ± 30	210 ± 30
	No. of tube segments	0	0
C	Length (mm)	1,070 ± 50	1,070 ± 50
	No. of tube segments	12	12
D	Length (mm)	450 ± 30	450 ± 30
	No. of tube segments	0	0
E	Length (mm)	320 ± 30	320 ± 30
	No. of tube segments	0	0
F	Length (mm)	675 ± 50	675 ± 50
	No. of tube segments	9	9
G	Length (mm)	250 ± 30	250 ± 30
	No. of tube segments	0	0
H	Length (mm)	600 ± 30	300 ± 30
	No. of tube segments	7	3
I	Length (mm)	–	300 ± 30
	No. of tube segments	–	4
J	Length (mm)	–	300 ± 30
	No. of tube segments	–	4
Donor and transfer tubes	External diameter (mm)	4.4 ± 0.1	4.4 ± 0.1
	Internal diameter (mm)	2.95 ± 0.05	2.95 ± 0.05
Red blood cell transfer tube "D"	External diameter (mm)	5.0 ± 0.1	5.0 ± 0.1
	Internal diameter (mm)	3.8 ± 0.1	3.8 ± 0.1

Code Structure

P	B	-	5	R	O	4	5	6	J	0	Y
1	2	3	4	5	6	7	8	9	10	11	12

Position	Description
1, 2, 3	PB- = Terumo Penpol blood bag
4	Bag configuration (1 = single, 2 = double ...)
5, 6	Anticoagulant and/or additive solution (see below)
7, 8	First 2 digits of the collection volume (35 = 350 mL and 45 = 450 mL)
9	Second digit of the gauge of the needle (6 = 16 G)
10	Type of label (see below)
11	Sampling or safety feature(s) (see next page)
12	Specific feature (Y = standard bag)

Solution Types

Code (RO)	Description
RO	Anticoagulant: CPD Additive solution: SAGM-2 (AS-5)*

Label Types

Code	Description
J	For use in India

Lot Number Structure

1	0	B	1	5	X	4
1	2	3	4	5	6	7

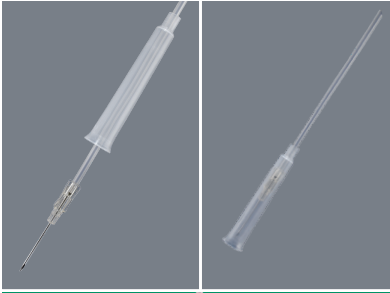
Position	Description
1, 2	Day of solution filling (10 = 10 th of the month)
3	Month of production represented by a letter from A to L (A = January, B = February ...)
4, 5	Last 2 digits of the year of production (15 = 2015)
6	Production line (X or Y)
7	Serial number of the batch that day (1 = first batch produced that day, 4 = fourth batch produced that day)

Composition of Solutions

Solution	Ingredients	g/100 mL
CPD	Citric acid monohydrate IP	0.327
	Sodium citrate dihydrate IP	2.630
	Sodium dihydrogen phosphate dihydrate IP	0.251
	Dextrose anhydrous equivalent to Dextrose monohydrate IP	2.550
	Water for injection IP	qs
SAGM- 2 (AS-5)*	Sodium chloride IP	0.877
	Adenine IP	0.030
	Dextrose anhydrous equivalent to Dextrose monohydrate IP	0.900
	Mannitol IP	0.525
	Water for injection IP	qs

*SAGM-2 and AS-5 solutions are the same with respect to ingredients and formulation.

Sampling and Safety Features



Needle injury protector (NIP): After removing the needle from the vein, the user slides the NIP cover over the needle and locks it.



Sampling arm (SA): The user diverts the first aliquot of blood through the sampling arm to collect samples for further testing.



Multi-sample luer adapter holder (holder): The adapter holder enables multiple samples using vacuum tubes.

Pre-donation sampling bag (PDSB): The user collects the first aliquot of blood from the donor in the pre-donation sampling bag to reduce the risk of contamination by skin bacteria. This blood can also be used for sampling.

Sampling and Safety Feature Configurations

Code	NIP	SA	HOLDER	PDSB
0	✓	✓	✓	✓

Terumo Penpol Private Limited

P.B. No. 6105, I-2, Jawahar Nagar
Kowdiar P.O.
Thiruvananthapuram – 695003
Kerala, India
Telephone: +91.471.301.5500/501
+91.471.714.5500/501
Email: penpol.info@terumobct.com
www.terumopenpol.com

**Due to continual development, specifications are likely to change without prior notice.

**For distribution in India Only



Terumo Blood and Cell Technologies is a medical technology company. Our products, software and services enable customers to collect and prepare blood and cells to help treat challenging diseases and conditions. Our employees around the world believe in the potential of blood and cells to do even more for patients than they do today. **TERUMOBCT.COM**

Terumo BCT, Inc.
Lakewood, CO, USA
+1.303.231.4357

Terumo BCT Europe N.V.
Zaventem, Belgium
+32.2.715.0590

Terumo BCT Asia Pte. Ltd.
Singapore
+65.6715.3778

Terumo BCT Latin America S.A.
Buenos Aires, Argentina
+54.11.5530.5200

Terumo BCT Japan, Inc.
Tokyo, Japan
+81.3.6743.7890