



## TOP AND BOTTOM BLOOD BAG SYSTEM WITH INTEGRAL LEUKOCYTE FILTER FOR RED BLOOD CELLS

TECHNICAL CARD

**TERUMO PENPOL®**

<b>Product Name</b>	<b>TOP AND BOTTOM BLOOD BAG SYSTEM WITH INTEGRAL LEUKOCYTE FILTER FOR RED BLOOD CELLS</b>
Description	Blood bag system containing CPD and SAGM-2 with an integral leukocyte filter for red blood cells.
Manufacturer	TERUMO PENPOL Private Limited., Puliarakonam, 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"> <li>Avoid excessive heat and direct sunlight. Protect from freezing.</li> <li>Store unused sets between 2 °C and 35 °C.</li> </ul>
Shelf life	<p>When stored under the specified conditions:</p> <ul style="list-style-type: none"> <li>24 months in the original unopened aluminum pouch</li> <li>15 days after opening the original aluminum pouch</li> </ul>
Conformities	<ul style="list-style-type: none"> <li>ISO 9001:2008</li> <li>ISO 13485:2003/EN ISO 13485:2012</li> <li>ISO 14001</li> <li>ISO 3826-1:2013</li> <li>ISO 3826-3:2006</li> </ul>

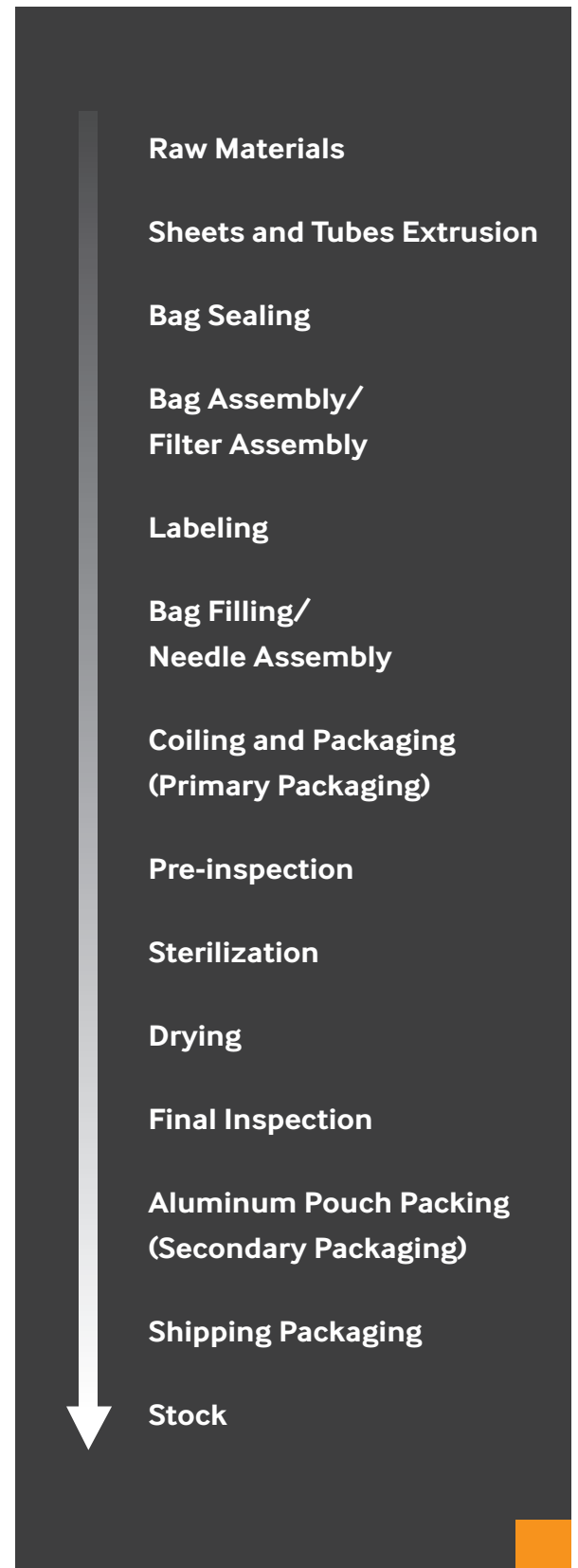
## General Features

Filter	<ul style="list-style-type: none"> <li>Asahi Sepacell® R-S01 high-efficiency leukocyte filter for red blood cells</li> </ul>
Plastic	<ul style="list-style-type: none"> <li>Polyvinyl Chloride (PVC) with DEHP</li> </ul>
Surface	<ul style="list-style-type: none"> <li>Embossed surface</li> </ul>
Needle	<ul style="list-style-type: none"> <li>Triple-bevel-cut needle with ultra-thin wall design</li> <li>Sand-blasted and silicon-lubricated cannula surface</li> </ul>
Tubes	<ul style="list-style-type: none"> <li>Embossed surface</li> <li>Unique sequence of numbers for identification</li> <li>Compatible with Terumo BCT sterile connection devices</li> </ul>
CLIKTIP valve	<ul style="list-style-type: none"> <li>Frangible connector that is opened by a double-bend movement</li> <li>Makes an audible "click" sound when opened</li> <li>Large inner diameter</li> </ul>
Mold	<ul style="list-style-type: none"> <li>One-piece weld with rounded corners</li> </ul>
Outlets	<ul style="list-style-type: none"> <li>Long-neck inner tube</li> <li>Tube dimension and diaphragm position are designed for spikes according to ISO 1135-4</li> </ul>
Labels	<ul style="list-style-type: none"> <li>Easy to write on</li> <li>Tamper-evident</li> <li>Single- or double-color graphics</li> <li>Dimensions comply with ISBT guidelines. 105 mm ± 5 mm × 105 mm ± 5 mm (H × W)</li> <li>Pre-printed with solution contents and bag type</li> </ul>
Barcode system	<ul style="list-style-type: none"> <li>ISBT 128 barcodes on bag labels</li> <li>GS1-128 barcodes on secondary packing and shipping carton</li> </ul>
Single pack	<ul style="list-style-type: none"> <li>Blood bags are sterilized in a polyester cast polypropylene over-wrap</li> </ul>
Aluminum pouch	<ul style="list-style-type: none"> <li>Airtight aluminum pouch</li> </ul>
Quality controls	<ul style="list-style-type: none"> <li>Physical, chemical, and biological tests of materials and final products comply with ISO 3826-1:2013 and USP standards.</li> </ul>

## Materials

Component	Material
Bag sheet	Extruded PVC (DEHP)
Tubes	Extruded PVC (DEHP)
Needle cannula	Stainless steel
Needle hub	Molded PVC
Needle protector	Inner: Molded PVC Outer: Molded polypropylene
Needle injury protector (NIP)	Molded PP
Outlet ports	Molded PVC
CLIKTIP valve cover	Moulded 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 packing (individual wrap foil)	Polyester cast polypropylene
Secondary packing (aluminum pouch)	Multi-layer laminated aluminum foil
Shipping box	Corrugated paper carton

## Production Flow (simplified)



## Blood Component Storage

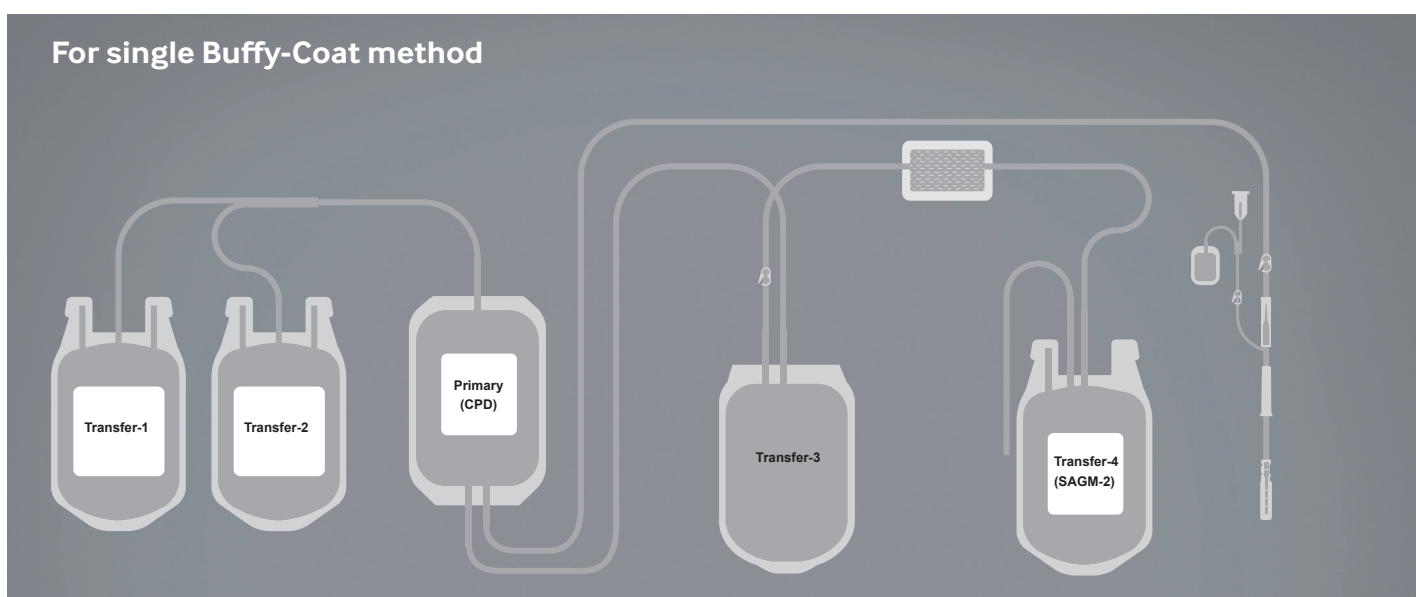
Component	Storage Condition
Whole Blood storage	CPD up to 21 days at 4° C ± 2° C
Red blood cell concentrate	CPD/ SAGM-2 up to 42 days at 4° C ± 2° C
Platelet concentrate	5 days at 22° C ± 2° C with slow and continuous agitation

## Product Range

Product Code	Configuration	Collection Volume	CPD Volume	SAGM-2 Volume	Transfer Bag 1	Transfer Bag 2	Transfer Bag 3	Transfer Bag 4
PB-5CO456JOY	Penta TAB blood bag with integral filter for red blood cells	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-5CO356JOY	Penta TAB blood bag with integral filter for red blood cells	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 & Bottom Configuration

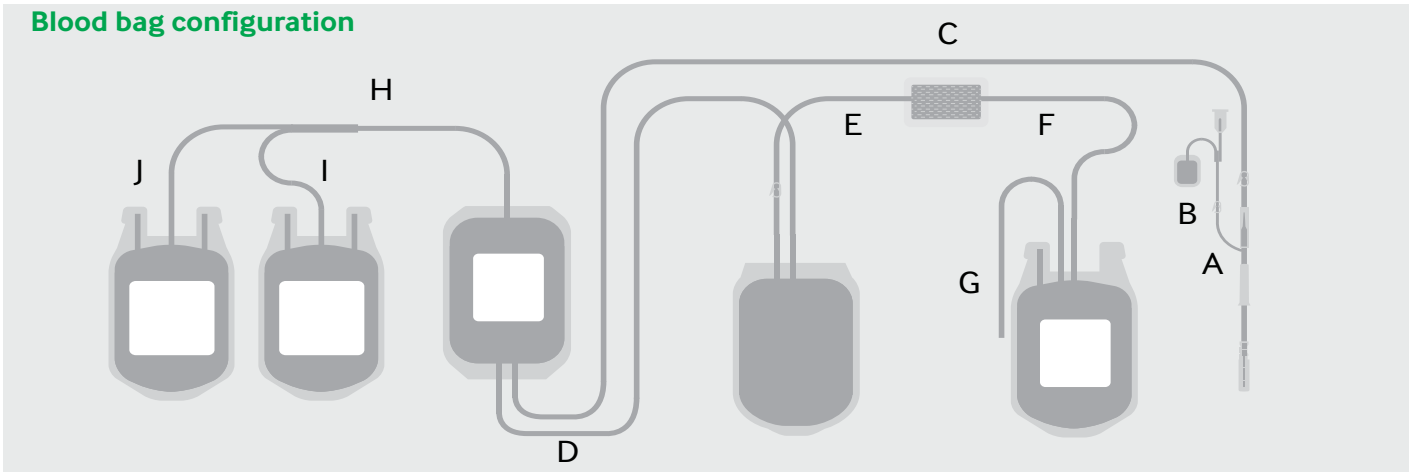
## Blood Bag Configuration



## Composition of Solutions

Solutions	Ingredients	g/100mL
CPD	Citric Acid (Monohydr.)	0.327
	Sodium Citrate (Dihydr.)	2.630
	Monobasic Sodium Phosphate (Dihydr.)	0.251
	Dextrose (Monohydr.)	2.550
	Water for injection	qs
SAGM-2	Sodium Chloride	0.877
	Adenine	0.030
	Dextrose (Monohydr.)	0.900
	Mannitol	0.525
	Water for injection	qs

## Blood bag configuration



## Technical Features




Product Code	Spec	PB- 5CO456J0Y	PB-5CO356J0Y
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	450/450/450/500/450	350/350/350/350/350
Needle size	Gauge	16	
Needle length	Length	38 mm ± 0.5 mm	
Primary bag (CPD)	Internal Height	175 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 Height	180 mm ± 5 mm	145 mm ± 5 mm
	Internal Width	125 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

Tube section			
A	Length	250 mm ± 30 mm	250 mm ± 30 mm
	Tube segments	0	0
B	Length	210 mm ± 30 mm	210 mm ± 30 mm
	Tube segments	0	0
C	Length	1070 mm ± 50 mm	1070 mm ± 50 mm
	Tube segments	12	12
D	Length	450 mm ± 30 mm	450 mm ± 30 mm
	Tube segments	0	0
E	Length	450 mm ± 30 mm	450 mm ± 30 mm
	Tube segments	0	0
F	Length	1070 mm ± 50 mm	1070 mm ± 50 mm
	Tube segments	12	12
G	Length	250 mm ± 30 mm	250 mm ± 30 mm
	Tube segments	0	0
H	Length	300 mm ± 30 mm	300 mm ± 30 mm
	Tube segments	4	4
I	Length	300 mm ± 30 mm	300 mm ± 30 mm
	Tube segments	4	4
J	Length	300 mm ± 30 mm	300 mm ± 30 mm
	Tube segments	4	4
Donor and transfer tubes	External diameter	4.4 mm ± 0.1 mm	4.4 mm ± 0.1 mm
	Internal diameter	2.95 mm ± 0.5 mm	2.95 mm ± 0.5 mm
Red blood cell transfer tube 'D'	External diameter	5.0 mm ± 0.1 mm	5.0 mm ± 0.1 mm
	Internal diameter	3.8 mm ± 0.1 mm	3.8 mm ± 0.1 mm



## Sampling and Safety Features

	<p><b>Needle injury protector (NIP):</b> The NIP is slid over the needle and locked after the needle is removed from the vein.</p>
	<p><b>Sampling arm (SA):</b> The first aliquot of blood is diverted through the sampling arm to collect samples for further testing.</p>
	<p><b>Multi-sample luer adapter holder (HOLDER):</b> The adapter holder enables multiple samples using vacuum tubes.</p> <p><b>Pre-donation bag (PDSB):</b> The first aliquot of blood from the donor is collected into the predonation bag to reduce the risk of contamination by skin bacteria. This blood can also be used for sampling.</p>

### Code Structure

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

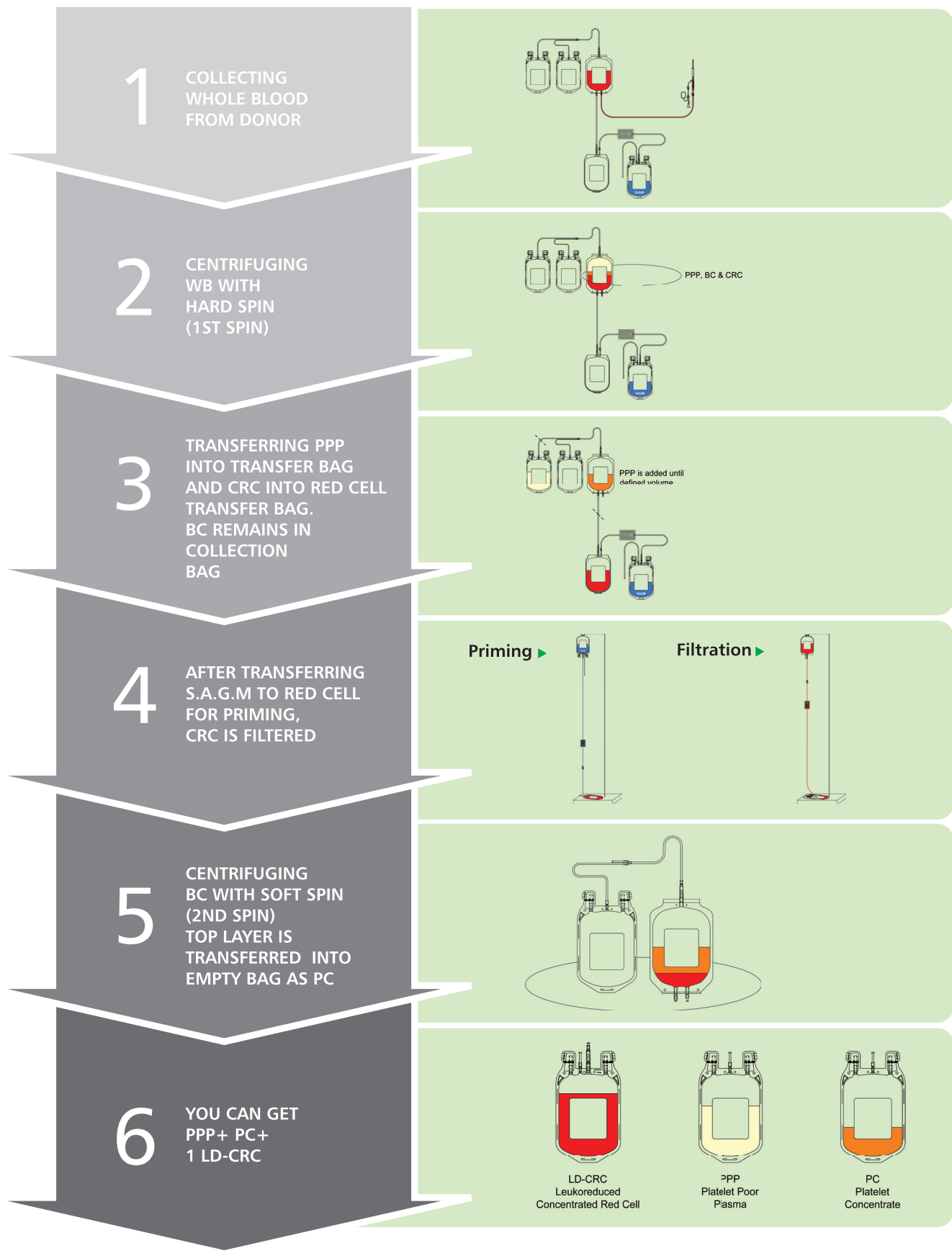
### Lot Number Structure

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

Position	Description
1, 2, 3	PB = Terumo Penpol blood bag
4	Type of bag (1 = single, 2 = double, 5=penta...)
5, 6	Type of anticoagulant and /or additive solution CO = CPD/SAGM-2
7, 8	Defines the collection volume by the first 2 digits (45 = 450 mL), (35 = 350 mL)
9	Second number of the gauge of the needle (6 = 16 g)
10	Country/language of the label (M = Multilingual, J = India)
11	Sampling or safety feature(s) (see earlier in brochure)
12	Specific feature (Y = standard bag)

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

# Process Diagram



# TERUMO PENPOL®

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\*\* Due to continuous development specifications are likely to change without prior notice

\*\* For distribution in India only