TERUMOBCT
Unlocking the Potential of Blood

TERUFLEX® BLOOD BAG CPDA-1

TECHNICAL CARD

Product Name	TERUFLEX® CPDA-1 Blood Bag
Description	Single-use, sterile polyvinyl chloride (PVC) blood bag system with citrate phosphate dextrose-adenine 1 (CPDA-1) anticoagulant solution
Legal manufacturer	Terumo BCT Ltd., Old Belfast Road, Millbrook, Larne, Co. Antrim, BT40 2SH, United Kingdom
Manufacturing site	Terumo BCT Vietnam Co., Ltd., A6, Long Duc Industrial Park, Long Thanh District, Dong Nai Province, Vietnam
Classification	Class IIb (MDD 93/42/EEC as amended by 2007/47/EC)
Sterilization	Steam sterilization
Storage conditions	▪ Avoid excessive heat and direct sunlight ▪ Protect from freezing ▪ Store unused sets between 1 °C and 35 °C
Shelf life	When stored under conditions specified in the instructions for use: 36 months in the original unopened aluminum pouch 15 days after opening the aluminum pouch
Conformities	▪ ISO 9001:2008 ▪ ISO 13485:2003 ▪ ISO 3826-1:2013 ▪ ISO 3826-2:2008 ▪ ISO 3826-3:2007

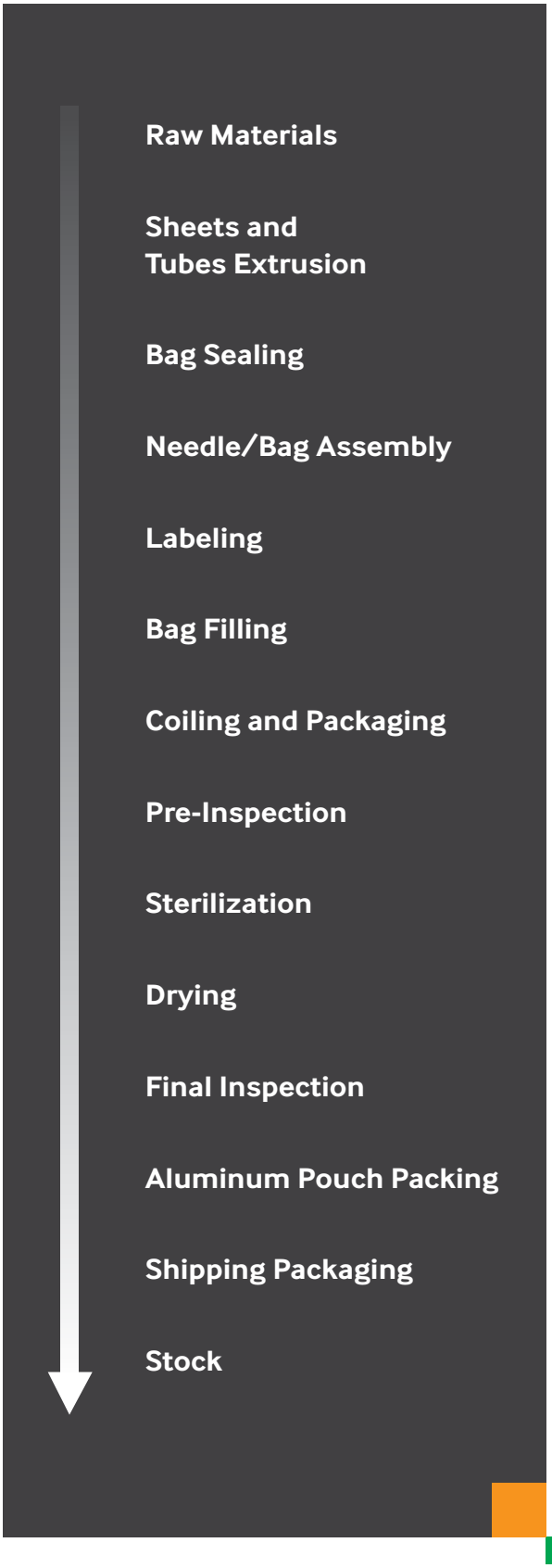
General Features

Plastic	▪ Polyvinyl chloride (PVC) with DEHP
Surface	▪ Embossed surface
Needle	▪ Triple-bevel-cut needle with an ultra-thin wall design ▪ Sand-blasted and silicon-lubricated cannula surface
Tubes	▪ Embossed surface ▪ Unique sequence of numbers for identification ▪ Compatible with Terumo BCT sterile connection devices
ClikTip valve	▪ Frangible connector is opened by a double-bend movement ▪ Makes an audible "click" sound when opened ▪ Has a large inner diameter
Mold	▪ One-piece weld with rounded corners
Outlets	▪ Long-neck inner tube ▪ Tube dimension and diaphragm position are designed for spikes according to ISO 1135-4
Labels	▪ Easy to write on ▪ Tamper-evident ▪ Single- or double-color graphics ▪ Compliant with ISBT guidelines for dimensions ▪ Pre-printed with solution contents and bag type ▪ Compliant with ISO 3826-2
Barcode system	▪ ISBT 128 barcodes on bag labels ▪ GS1-128 barcodes on secondary packing and shipping carton
Single pack	▪ Blood bags are sterilized in a polyester cast polypropylene (PP) over-wrap
Aluminum pouch	▪ Airtight aluminum pouch

Materials

Component	Material
Bag sheet	Extruded PVC
Tubes	Extruded PVC
Needle cannula	Stainless steel
Needle hub	Molded PVC
Needle protector	Inner: Molded PVC Outer: Molded PP
NIP	Molded PP
Outlet ports	Molded PVC
ClikTip valve cover	Extruded PVC
ClikTip valve body	Molded polycarbonate (PC)
Y connector	Molded PVC
Sampling needle	PC hub/stainless steel Needle/isoprene sheath
Holder	Molded PP
Pre-donation sampling bag	Extruded PVC
Clamp	Molded polyacetal
Primary packing (individual wrap foil)	Polyester cast PP
Secondary packing (aluminum pouch)	Multi-layer laminated aluminum foil
Shipping box	Corrugated paper carton

Production Flow (simplified)



Quality Controls

FUNCTIONAL TESTS:

Needle tube assembly strength
Centrifugation resistance (5,000 g × 10')
Pressure resistance (0.7 kg/cm^2 × 10')
Thermal resistance (–80 °C to 37 °C ± 2 °C)

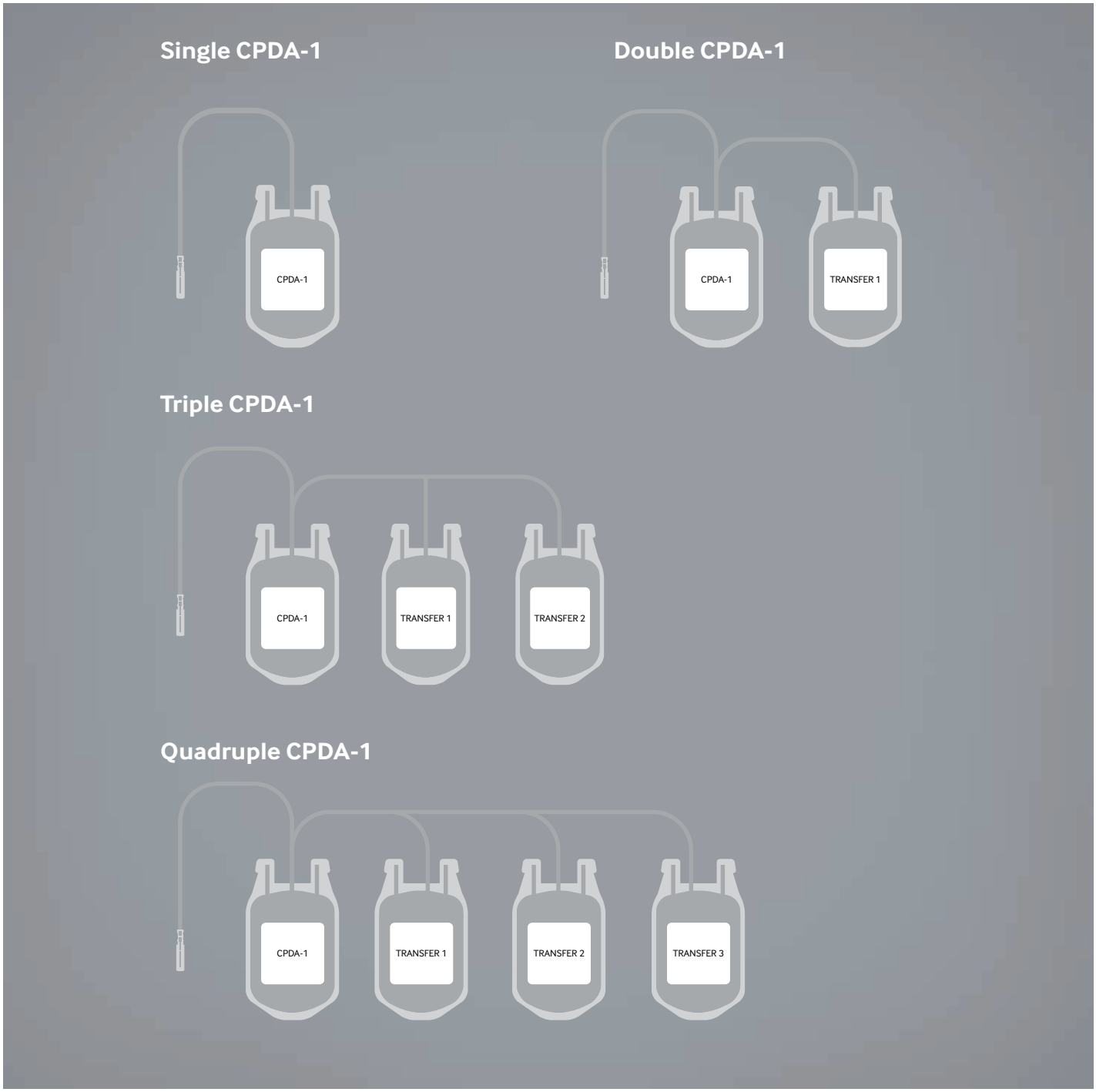
RAW MATERIALS PURITY AND COMPOSITION:

Ashes (< 1 mg/g)
Heavy metals (Pb ≤ 1 ppm and Cd ≤ 1 ppm)
Additive solution chemical control
Solutions—physical and chemical features pH test
Chloride test (< 35 ppm)

BIOLOGICAL TESTS:

Bag sterility (EP, USP)
Surface microbiological control
Bacterial endotoxin
Acute toxicity control

Blood Bag Configuration



Composition of Anticoagulant

Solutions	Ingredients	g/100 mL
Anticoagulant CPDA-1	Citric Acid (Anhydr.)	0.299
	Sodium Citrate (Dihydr.)	2.630
	Monobasic Sodium Phosphate (Monohydr.)	0.222
	Dextrose (Monohydr.)	3.190
	Adenine	0.0275
	Water for injection	qs

Blood Component Storage

Component Storage	Storage Condition
Whole Blood	CPDA-1 up to 35 days at 4 ˚C ± 2 ˚C
Red Blood Cell (RBC) Concentrate	CPDA-1 up to 35 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	CPDA-1 Volume	Transfer Bag 1	Transfer Bag 2	Transfer Bag 3
1CD256E%	Single blood bag	250 mL	35 mL	—	—	—
1CD356E%		350 mL	49 mL			
1CD456E%		450 mL	63 mL			
2CD256E%	Double blood bag	250 mL	35 mL	Empty transfer bag suitable for storage of Plasma	—	—
2CD356E%		350 mL	49 mL			
2CD456E%		450 mL	63 mL			
3CD356E%	Triple blood bag	350 mL	49 mL	Empty transfer bag suitable for storage of RBCs, Plasma or 5-day Platelet		—
3CD456E%		450 mL	63 mL			
4CD456E%	Quadruple blood bag	450 mL	63 mL	Empty transfer bag suitable for storage of RBCs, Plasma, dry or diluted Buffy Coat preparation or 5-day Platelet		

% Represents the safety feature version.
Refer to the Code Structure section on the following pages for additional information.

Safety Feature Version

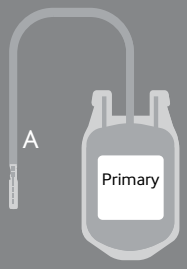
Code (%)	NIP	HOLDER	PDSB
0	✓	✓	✓
8	–	–	–

NIP: Needle injury protector
HOLDER: Multi-sample luer adapter holder
PDSB: Pre-donation sampling bag

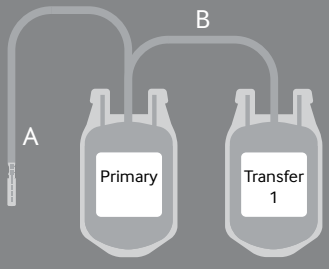
Technical Features

Product Code	Spec.	1CD256E%	1CD356E%	1CD456E%	2CD256E%	2CD356E%	2CD456E%
Collection volume	mL	250	350	450	250	350	450
Transfer bag volume	mL	–	–	–	250	350	450
Needle length (mm)	Length	38 ± 0.5					
Primary bag size (mm)	Internal height	130 ± 5	160 ± 5	180 ± 5	130 ± 5	160 ± 5	180 ± 5
	Internal width	120 ± 5					
Transfer bags 1, 2 and 3 size (mm)	Internal height	–	–	–	130 ± 5	160 ± 5	180 ± 5
	Internal width	–	–	–	120 ± 5		
Donor tube diameter (mm)	Internal	3.0 ± 0.1					
	External	4.4 ± 0.1					
Donor tube length (mm)	A	980 ± 40					
Transfer tube length (mm)	B	–	–	–	540 ± 25		
	C	–	–	–	–	–	–
	D	–	–	–	–	–	–
	E	–	–	–	–	–	–
	F	–	–	–	–	–	–
Donor tube segment	A	12					
Transfer tube segments	B	–	–	–	8		
	C	–	–	–	–	–	–
	D	–	–	–	–	–	–
	E	–	–	–	–	–	–
	F	–	–	–	–	–	–

Single CPDA-1



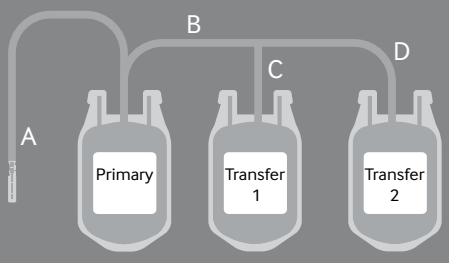
Double CPDA-1



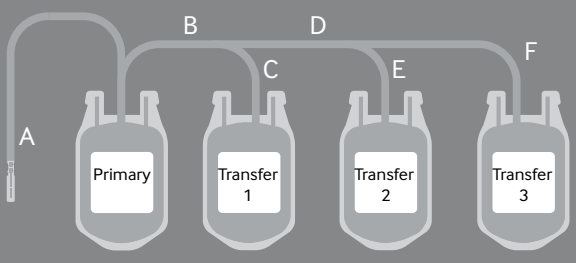
Technical Features

Product Code	Spec.	3CD356E%	3CD456E%	4CD456E%
Collection volume	mL	350	450	450
Transfer bag volume	mL	350/350	450/450	450/450/450
Needle length (mm)	Length	38 ± 0.5		
Primary bag size (mm)	Internal height	160 ± 5	180 ± 5	
	Internal width	120 ± 5		
Transfer bags 1, 2 and 3 size (mm)	Internal height	160 ± 5	180 ± 5	
	Internal width	120 ± 5		
Donor tube diameter (mm)	Internal	3.0 ± 0.1		
	External	4.4 ± 0.1		
Donor tube length (mm)	A	980 ± 40		
Transfer tube length (mm)	B	260 ± 15		230 ± 15
	C	260 ± 15		
	D	260 ± 15		125 ± 10
	E	–	–	260 ± 15
	F	–	–	260 ± 15
Donor tube segment	A	12		
Transfer tube segments	B	4	4	0
	C	4		
	D	4	4	0
	E	–	–	4
	F	–	–	4

Triple CPDA-1



Quadruple CPDA-1



Code Structure (Example)

4	C	D	4	5	6	E	0
1	2	3	4	5	6	7	8

Position	Description
1	Type of bag (1 = single, 2 = double …)
2, 3	Type of additive solution and/or anticoagulant (CD = CPDA-1)
4, 5	First two digits of the collection volume (25 = 250 mL, 35 = 350 mL, 45 = 450 mL)
6	Second number of the gauge of the needle (6 = 16 G, 7 = 17 G)
7	Country/language of the label (M = Multilingual, Z = Latin American Spanish, E = English, L = Sri Lanka, S = symbol …)
8	Type of sampling or safety feature (0 = full safety feature*, 8 = no safety feature)

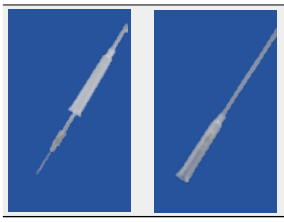
*Full safety feature includes NIP, HOLDER, and PDSB (see below).

Lot Number Structure (Example)

1	6	0	1	1	2	A	1	5	1
1	2	3	4	5	6	7	8	9	10

Position	Description
1, 2	Last two digits of the year of production (16 = 2016)
3, 4	Month of production
5, 6	Date of production
7	Solution filling line (A and B)
8	Serial number of the batch produced that day (1 = first batch, 4 = fourth batch …)
9	Vietnam plant code
10	Configuration

Sampling and Safety Features



Needle injury protector (NIP): The NIP is slid over the needle and locked after the needle is removed from the vein.

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

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

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

Manufactured by Terumo BCT Ltd.
Available in select markets.

TERUMOBCT

As a global leader in blood component, therapeutic apheresis and cellular technologies, we believe in the potential of blood to do even more for patients than it does today. This belief inspires our innovation and strengthens our collaboration with customers.

UNLOCKING THE POTENTIAL OF BLOOD | TERUMOBCT.COM

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