### **TERUMO PENPOL®**

# **BLOOD BAGS**

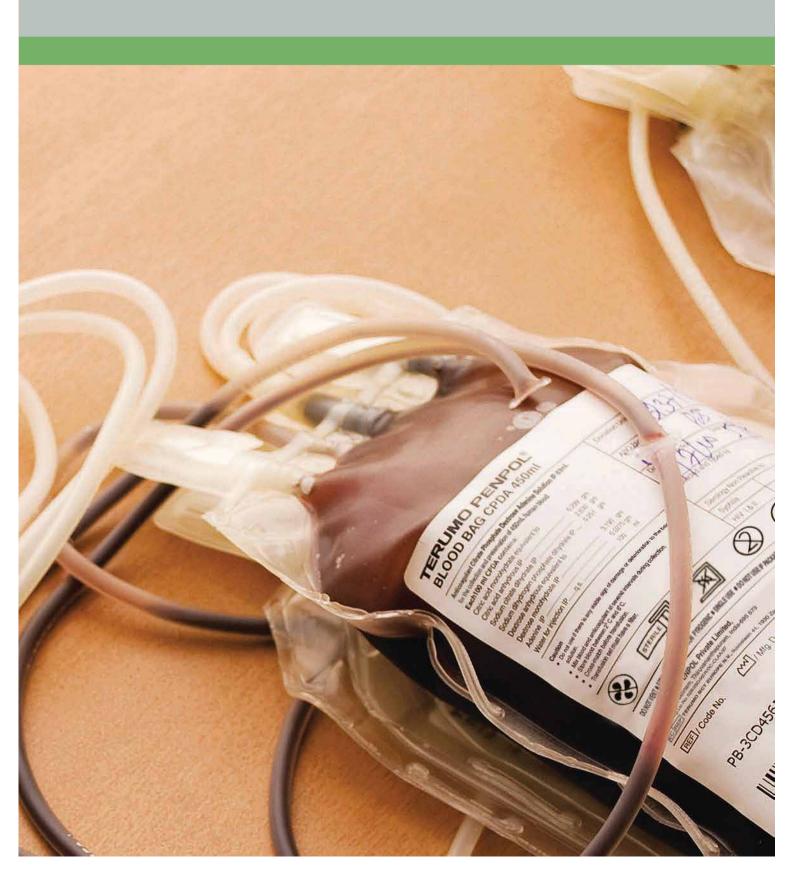
Promoting repeat voluntary blood donation and optimizing blood component processing











Terumo Penpol blood bags are sold in over 75 countries

Over 100 million blood bags have been manufactured

Over 22,500 pieces of medical equipment have been manufactured

Started as the first Indian manufacturer of blood bags, Terumo Penpol continues to be the market leader in India in the field of equipment and disposables for the Blood Transfusion industry. With a comprehensive range of products covering collection, processing, storage and issue of blood, Terumo Penpol continues to serve the leading blood banks in India and around the world. Terumo Penpol is now a subsidiary of the \$4.5 billion Terumo Corporation, Japan and is a group company of Terumo BCT, USA which leads the Blood Management business of Terumo.



#### **TERUMO PENPOL BLOOD BAGS**

The disposable blood bag is Terumo Penpol's signature product. Terumo Penpol is the market leader in blood bags and related medical equipment because of the superior technology, service and commitment that goes into every product. The manufacturing process at Terumo Penpol provides assurance that products of consistently high quality which meet the desired specifications are produced every time.

The advanced technology that goes into the production of blood bags is acknowledged as among the best in the market. The durable material of the blood bags is complemented by advanced methods of filtering and filling anticoagulants. Terumo Penpol uses top quality imported PVC compounds and high end technology for sheet extrusion, which are then converted into bags using high frequency sealing machines. These bags are able to withstand enormous forces during centrifugation.

The entire range of Terumo Penpol collection devices follow good manufacturing processes in order to make the blood collection experience safe, convenient and comfortable for the provider while assuring quality for the end user. Blood collection is done either in blood banks or donation camps. It is extremely important to make the process safe and convenient.













# **QUALITY FIRST**

Terumo Penpol's superior technology is acknowledged as among the best in the market. The equipment used in the manufacturing processes are subjected to validation procedures. Critical process parameters are defined and followed to obtain high quality products. The Sterilization process at Terumo Penpol provides a Sterility Assurance Level of 10<sup>-6</sup>.



#### High molecular weight PVC

 Bags are made with high molecular weight PVC to ensure better tensile strength and weld strength

## Advanced sheet extrusion technology

- Ensures uniform extrusion of sheet
- Prevents breakage during centrifugation



# Advanced high frequency bag sealing technology

- Ensures weld strength which can withstand high centrifugal force
- Ensures adequate weld bead formation
- Weld strength of blood bags are confirmed by balloon and ageless testing



#### Triple filtration of anticoagulant

• Triple filtration ensures anticoagulant without any contaminant



## Automatic filling of anticoagulant

 Anticoagulant is filled in the bags automatically to ensure accuracy



#### Advanced coiling method

- Advanced and standardized coiling method
- Blood Bag coiling is done through a conveyor to prevent kinks, which ensures a free flow during collection and separation



## Sterilization process with automatic data logger

- Validated sterilization process as per ISO 17665-1
- The process is PLC controlled.
- Sterility test is performed after this process of Superheated Water Spray Sterilization.

# CUSTOMER FIRST

State-of-the-art blood bags and related equipment allows for the ease and maximization of blood collection, storage and processing, ensuring that customer satisfaction remains the ultimate goal. Terumo Penpol ensures that its Customer First and Quality First approach is a company wide policy - all activities are carried out through this unique approach.



#### **Packaging**

- Secondary packaging is made of multilayer laminated Aluminium pouch
- Reduces moisture loss
- Protects bag from damage
- Barcoding of secondary packing and shipping cartons are with GS1-128



#### **Outlet Port Pouch**

 Each outlet port is fitted with a hermetically sealed tamper evident protector to maintain sterility of the internal surface



#### **Tubing**

- Memoryless tubing ensures smooth flow of blood components without damage during blood collection
- Very clear thermal transfer printing for easy identification of pilot samples
- Stable wall thickness and inner diameter ensures the smooth flow and collection of blood



#### Needle

- Triple bevel cut needle with ultra thin walled design.
- Sand blasted and silicon lubricated surface of the cannula ensures smooth and painless venipuncture
- Black bevel indicator mark provided on needle hub for performing phlebotomy with needle bevel up for smooth venipuncture
- Low penetration force, hence less pain during phlebotomy

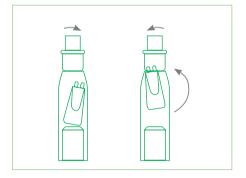
## Needle Protector: Composed of two parts

- The outer layer is made of hard polypropylene to ensure rigidity of cap
- The inner layer is made of soft PVC to ensure hermetic closure with the hub
- Tamper evident



#### Label

- Clear, easy to understand labels
- Nontoxic adhesive
- Resistant to tear, water and centrifugation force
- Product labels are bar coded as per ISBT 128 standard



#### Break off valve (CLIK TIP)

- The big break off valve helps in a smooth flow of component and reduces processing time
- The uniform break force of the break off valve ensures easy breakability

#### **Sheet material**

- Ideal for storing red cell, plasma and platelet
- Platelet bags are designed for 5 day platelet storage

# SAFETY FIRST

Occupational exposure to blood remains a serious concern during the blood donation process. In order to address the safety issues concerning the blood bank personnel, we have introduced a range of features in our blood bags. The collection and sampling features are available in all configurations of blood bags.







#### Needle injury protector (NIP)

- Provides immediate shielding of needle on withdrawal from vein.
- Reduces the risk of needlestick injuries for the phlebotomist during collection.
- Improves safety in blood banks.

## Sampling arm with Luer Adaptor

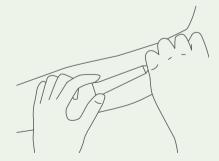
- Facilitates safe in-line sampling.
- Enables multiple sampling using vacuum tubes.
- Makes sample collection procedure easy and safe

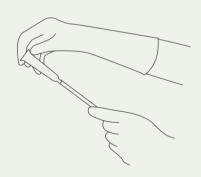
### Pre-donation bag (PDB)

- Diverts 20-25 ml of initial blood
- Enables diversion and collection of the first amount of blood which usually contains skin particles and bacteria
- Risk of bacterial sepsis is minimized
- \* Reference: 30% of bacterial contamination is due to normal skin flora. Approximately 56% are gram positive bacteria (Trans med 1998; 8;19-22)

#### How to use the Needle Injury Protector







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 withdrawn into the NIP to it's base & lock to ensure that it is unexposed.

## TOP AND BOTTOM BAGS FOR BUFFY COAT METHOD



Terumo Penpol Quadruple Top and Bottom bags are widely used for component preparation using the buffy coat method. T-ACE II+ integration helps in a standardized component preparation.

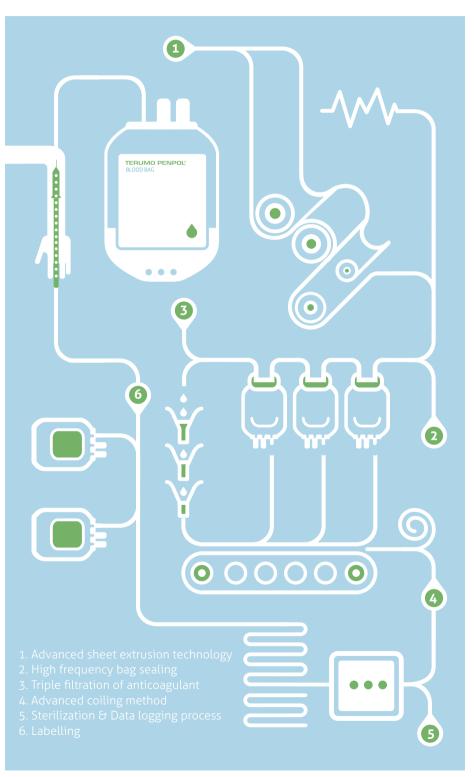
In TAB bag system the advantage is that after initial hard spin, red cells and plasma can be simultaneously separated with the help of T-ACE II+.Red cells will go to SAGM-2 bag at the bottom and plasma will move to plasma bag at the top.The platelet is then prepared from the buffy coat, which is widely recommended for platelet preparation.



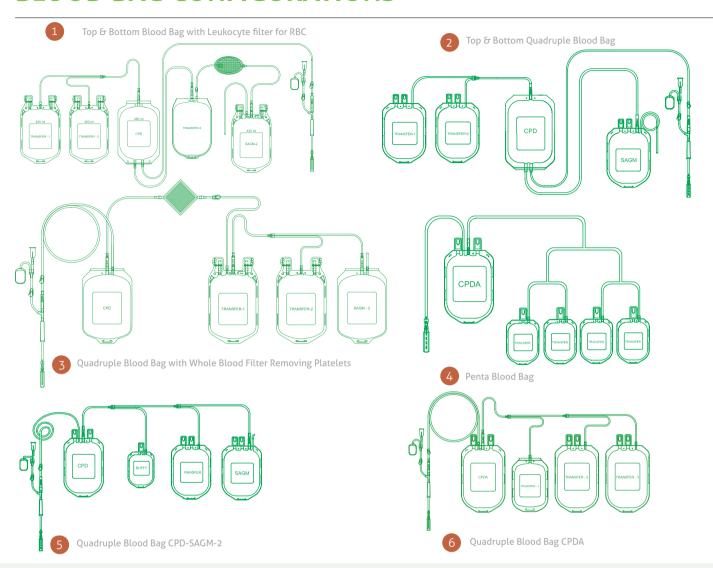
Specially-designed Terumo Penpol Quadruple Top and Top bags of 350 ml and 450 ml capacity are also available for the buffy coat method to optimize blood donations.

#### TERUMO PENPOL QUALITY CONTROL & QUALITY ASSURANCE

The Terumo Penpol Quality Control & Quality Assurance department is manned by by qualified and experienced personnel. All incoming raw materials are subjected to stringent quality checks. Suppliers are audited at regular intervals to ensure that they meet the high standards set by Terumo Penpol. The in-process and finished product analysis are based on defined procedures using standardized instruments. The documentation activities are carried out as per regulatory requirements. Traceability is ensured at every stage in the manufacturing process.



## **BLOOD BAG CONFIGURATIONS**



# 1 Top & Bottom Blood Bag with Leukocyte filter for RBC

Top and Bottom Penta blood bags with a CRC filter for whole blood collection and separation of 3 different blood components (leukodepleted red blood cells, plasma and platelets). The primary bag contains CPD solution and one satellite bag is attached to a CRC filter. The satellite bag comes with SAGM-2 solution for red cell preservation. Platelets are prepared by the buffy coat method. One transfer bag is valid for 5 day of platelet storage.

### 4 Penta Blood Bag

Designed for paediatric/multiple transfusions. Reduces the risk of multiple donor exposure to paediatric patients. Prevents wastage of blood as one unit can be given to 5 different recipients.

### 2 Top & Bottom Quadruple Blood Bag

Top and Bottom Quadruple blood bags for whole blood collection and separation of 3 different blood components (red blood cells, plasma and platelets). The primary bag contains CPD solution and one satellite bag comes with SAGM-2 solution for red cell preservation. Platelets are prepared by the buffy coat method. One transfer bag is valid for 5 days of platelet storage.

#### 5 Quadruple Blood Bag CPD-SAGM-2

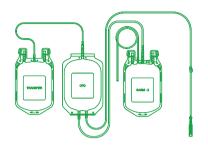
Quadruple blood bag with SAGM-2 for whole blood collection and separation of 3 different blood components (red blood cells, plasma and platelets) through the buffy coat method. The primary bag contains CPD solution and has 3 satellite bags. One satellite bag is of 100ml capacity to prepare platelets through the buffy coat method. One satellite bag is valid for 5 days of platelet storage.

#### Quadruple Blood Bag with Whole Blood Filter Removing Platelets

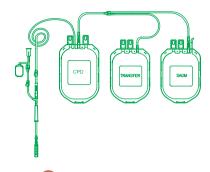
Quadruple Blood Bag with Integral Whole Blood Filter Removing Platelets for whole blood collection and separation of 2 different blood components (leukodepleted red blood cells and leukodepleted plasma). The primary bag contains CPD solution and is attached to a WB-RP filter. One satellite bag comes with SAGM-2 solution for red cell preservation.

### 6 Quadruple Blood Bag CPDA

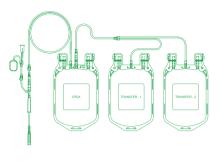
Quadruple blood bag for whole blood collection and separation of 3 different blood components (red blood cells, plasma and platelets) through the buffy coat method. The primary bag contains CPDA solution and has 3 satellite bags. One satellite bag is of 100ml capacity to prepare platelets through the buffy coat method. One satellite bag is valid for 5 days of platelet storage.



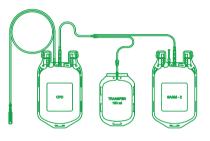




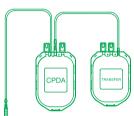
8 Triple blood bag CPD-SAGM-2



9 Triple blood bag CPDA



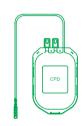




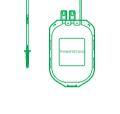












14 Blood Transfer Bag

## 7 Top & Bottom Triple Blood Bag

Top and Bottom Triple blood bags for whole blood collection and separation of 2 different blood components (red blood cells, plasma). The primary bag contains CPD solution and one satellite bag comes with SAGM-2 solution for red cell preservation. Components are prepared using the buffy coat method.

10 Double Blood Bag CPD-SAGM-2

For whole blood collection and separation of 2 different blood components (red blood cells, and plasma). Inclusion of additive solution helps extend the shelf life of red cells to 42 days.

13 Cord Blood Collection Bag

For collection of Umbilical Cord Blood. Each bag comes with a secondary packing of multilayer laminated Aluminium pouch for the convenience of cord blood collection centers. 8 Triple blood bag CPD-SAGM-2

Triple blood bag with SAGM-2 for whole blood collection and separation of 3 different blood components (red blood cells, plasma and platelets). The primary bag contains CPD and one satellite bag contains SAGM-2 solution.

11 Double Blood Bag CPDA

For whole blood collection and separation of 2 different blood components (red blood cells, and plasma) obtained through the process of centrifugation and extraction.

**14** Blood Transfer Bag

For use with blood bag for transfer or pooling of blood and blood components.

Triple blood bag CPDA

Triple blood bag for whole blood collection and separation of 3 different blood components (red blood cells, plasma and platelets). The primary bag contains CPDA solution and is attached to 2 satellite bags

Single Blood Bag

For whole blood collection. The bag contains CPDA solution.

Product Code	Description
PB-1CD106J8B	Single Blood Bag CPDA 100ml
PB-1CD356J0B	Single Blood Bag CPDA 350ml with NIP, Luer Adaptor and PDB
PB-1CD356J5Y	Single Blood Bag CPDA 350 ml with NIP
PB-1CD356J8B	Single Blood Bag CPDA 350 ml
PB-1CD356J8Y	Single Blood Bag CPDA 350ml
PB-1CD456J0B	Single Blood Bag CPDA 450ml with NIP, Luer Adaptor and PDB
PB-1CD456J8B	Single Blood Bag CPDA 450ml
PB-1CD456J8Y	Single Blood Bag CPDA 450ml
PB-1PD156J5S	Single Cord Blood Bag CPD 150ml with NIP
PB-1PD156J8S	Single Cord Blood Bag CPD 150ml
PB-1PD256J8S	Single Cord Blood Bag CPD 250ml
PB-1TR101J8B	Blood Bag Transfer 100 ml
PB-1TR301J8B	Blood Bag Transfer 300ml
PB-1TR451J8B	Blood Bag Transfer 450ml
PB-2CD356J0B	Double Blood Bag CPDA 350ml with NIP, Luer Adaptor and PDB
PB-2CD356J1B	Double Blood Bag CPDA 350ml with Sampling arm, NIP and PDB
PB-2CD356J1Y	Double Blood Bag CPDA 350ml with Sampling arm, NIP and PDB
PB-2CD356J5B	Double Blood Bag CPDA 350ml with NIP
PB-2CD356J5Y	Double Blood Bag CPDA 350ml with NIP
PB-2CD356J8B	Double Blood Bag CPDA 350ml
PB-2CD356J8Y	Double Blood Bag CPDA 350ml
PB-2CD456J0B	Double Blood Bag CPDA 450ml with NIP, Luer Adaptor and PDB
PB-2CD456J5B	Double Blood Bag CPDA 450 ml with NIP
PB-2CD456J8B	Double Blood Bag CPDA 450ml
PB-2CD456J8Y	Double Blood Bag CPDA 450ml
PB-3A0356J0B	Triple Blood Bag CPD SAGM-2 350ml with NIP, Luer Adaptor and PDB
PB-3A0356J0Y	Triple Blood Bag CPD SAGM-2 350ml with NIP, Luer Adaptor and PDB
PB-3A0356J6B	Triple Blood Bag CPD SAGM-2 350ml with Luer Adaptor
PB-3A0356J6Y	Triple Blood Bag CPD SAGM-2 350ml with Luer Adaptor
PB-3A0356J8B	Triple Blood Bag CPD SAGM-2 350ml
PB-3A0356J8X	Triple Blood Bag CPD SAGM-2 350ml
PB-3A0356J8Y	Triple Blood Bag CPD SAGM-2 350ml
PB-3A0456J0B	Triple Blood Bag CPD SAGM-2 450ml with NIP, Luer Adaptor and PDB
PB-3A0456J0Y	Triple Blood Bag CPD SAGM-2 450ml with NIP, Luer Adaptor and PDB
PB-3A0456J8B	Triple Blood Bag CPD SAGM-2 450ml
PB-3A0456J8Y	Triple Blood Bag CPD SAGM-2 450ml
PB-3A0456J8X	Triple Blood Bag CPD SAGM-2 450ml Buffy
PB-3B0356J8Y	Triple Blood Bag CPD SAGM-2 350mL Top & Bottom
PB-3B0356J0Y	Triple Blood Bag CPD SAGM-2 Top & Bottom 350ml with NIP, Luer Adaptor and PDB
PB-3B0456J0Y	Triple Blood Bag CPD SAGM-2 Top & Bottom 450ml with NIP, Luer Adaptor and PDB
PB-3B0456J8Y	Triple Blood Bag CPD SAGM-2 450mL Top & Bottom
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Product Code	Description
PB-3CD356J8B	Triple Blood Bag CPDA 350ml
PB-3CD356J8Y	Triple Blood Bag CPDA 350ml
PB-3CD456JOY	Triple Blood Bag CPDA 450ml with NIP, Luer Adaptor and PDB
PB-3CD456J5B	Triple Blood Bag CPDA 450ml with NIP
PB-3CD456J8B	Triple Blood Bag CPDA 450ml
PB-3CD456J8Y	Triple Blood Bag CPDA 450ml
PB-4A0356J0A	Quadruple Blood Bag CPD SAGM-2 350ml Buffy with NIP, Luer Adaptor and PDB
PB-4A0356J6B	Quadruple Blood Bag CPD SAGM-2 350ml with Luer Adaptor
PB-4A0356J8A	Quadruple Blood Bag CPD SAGM-2 350ml Buffy
PB-4A0356J8B	Quadruple Blood Bag CPD SAGM-2 350ml
PB-4A0356J8X	Quadruple Blood Bag CPD SAGM-2 350ml Buffy
PB-4A0356J8Y	Quadruple Blood Bag CPD SAGM-2 350ml
PB-4A0456J0A	Quadruple Blood Bag CPD SAGM-2 450ml Buffy with NIP, Luer Adaptor and PDB
PB-4A0456J5A	Quadruple Blood Bag CPD SAGM-2 450ml Buffy with NIP
PB-4A0456J8A	Quadruple Blood Bag CPD SAGM-2 450ml Buffy
PB-4A0456J8B	Quadruple Blood Bag CPD SAGM-2 450ml
PB-4A0456J8X	Quadruple Blood Bag CPD SAGM-2 450ml Buffy
PB-4A0456J8Y	Quadruple Blood Bag CPD SAGM-2 450ml
PB-4B0356J0Y	Quadruple Blood Bag CPD SAGM-2 Top & Bottom 350ml with NIP, Luer Adaptor and PDB
PB-4B0356J8Y	Quadruple Blood Bag CPD SAGM-2 Top & Bottom 350ml
PB-4B0456J0B	Quadruple Blood Bag CPD SAGM-2 Top & Bottom 450ml with NIP, Luer Adaptor and PDB
PB-4B0456J5B	Quadruple Blood Bag CPD SAGM-2 Top & Bottom 450ml with NIP
PB-4B0456J8B	Quadruple Blood Bag CPD SAGM-2 Top & Bottom 450ml
PB-4B0456J8Y	Quadruple Blood Bag CPD SAGM-2 Top & Bottom 450ml
PB-4B0456P0B	Quadruple Blood Bag CPD SAGM-2 Top & Bottom 450ml with NIP, Luer Adaptor and PDB
PB-4CD356J8Y	Quadruple Blood Bag CPDA 350ml
PB-4CD456JOA	Quadruple Blood Bag CPDA 450ml Buffy with NIP, Luer Adaptor and PDB
PB-4CD456J8A	Quadruple Blood Bag CPDA 450ml Buffy
PB-4CD456J8B	Quadruple Blood Bag CPDA 450ml
PB-4CD456J8X	Quadruple Blood Bag CPDA 450ml Buffy
PB-4CD456J8Y	Quadruple Blood Bag CPDA 450ml
PB-4C0456J0B	Quadruple Blood Bag CPD SAGM-2 Top & Bottom CRC 450ml with NIP, Luer Adaptor and PDB
PB-4R0456J0Y	Quadruple Blood Bag CPD SAGM-2 Top & Bottom CRC 450ml with NIP, Luer Adaptor and PDB
PB-4C0356J0Y	Quadruple Blood Bag CPD SAGM-2 Top & Bottom CRC 350ml with NIP, Luer Adaptor and PDB
PB-4R0356J0Y	Quadruple Blood Bag CPD SAGM-2 Top & Bottom CRC 350ml with NIP, Luer Adaptor and PDB
PB-4W0456J0Y	Quadruple Blood Bag CPD SAGM-2 450ml Inline Whole Blood Filter with NIP, Luer Adaptor and PDB
PB-5CD456J8B	Penta Blood Bag CPDA 450ml
PB-5C0356J0Y	Penta Blood Bag CPD SAGM-2 Top & Bottom CRC 350ml with NIP, Luer Adaptor and PDB
PB-5R0356J0Y	Penta Blood Bag CPD SAGM-2 Top & Bottom CRC 350ml with NIP, Luer Adaptor and PDB
PB-5C0456J0B	Penta Blood Bag CPD SAGM-2 Top & Bottom CRC 450ml with NIP, Luer Adaptor and PDB
PB-5C0456J0Y	Penta Blood Bag CPD SAGM-2 Top & Bottom CRC 450ml with NIP, Luer Adaptor and PDB
PB-5RO456JOY	Penta Blood Bag CPD SAGM-2 Top & Bottom CRC 450ml with NIP, Luer Adaptor and PDB

### TERUMO PENPOL®

#### REGISTERED OFFICE

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 $<sup>^{**}</sup>$  Due to continuous development specifications are likely to change without prior notice  $^{**}$  For distribution in India only