REVEOS SELECT CPD/AS-5 RED CELL PRESERVATIVE FOR COLLECTION OF BLOOD- dextrose monohydrate, trisodium citrate dihydrate, anhydrous citric acid, and sodium phosphate, monobasic, unspecified form solution

Terumo BCT Vietnam CO., Ltd.

HIGHLIGHTS OF PRESCRIBING INFORMATION
REVEOS® SELECT SET
CPD WITH AS-5 RED CELL PRESERVATIVE SOLUTION FOR COLLECTION OF 500 mL OF BLOOD
Terumo BCT, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use the Reveos SELECT set safely and effectively. See full prescribing information for the Reveos SELECT set.

REVEOS SELECT SET

Sterile Fluid
PVC Plasticized With DEHP Bag

Initial U.S. Approval: TBD

INDICATIONS AND USAGE

- The Reveos® SELECT set is intended to collect a unit of whole blood and to process the whole blood unit on the Reveos Automated Blood Processing System, producing blood components. (1)
- Rx only. (1)

DOSAGE AND ADMINISTRATION

- Follow the instructions for collecting blood with the Reveos SELECT set. (2)
- Follow the instructions for post-processing and red blood cell leukoreduction with the Reveos SELECT set. (2)

DOSAGE FORMS AND STRENGTHS

- 70 mL Citrate Phosphate Dextrose (CPD) anticoagulant sterile fluid in a PVC plasticized with DEHP bag. (3)
- 111 mL Additive Solution 5 (AS-5) red cell preservative solution sterile fluid in a PVC plasticized with DEHP bag. (3)

CONTRAINDICATIONS

- None. (4)

WARNINGS AND PRECAUTIONS

- Do not reuse. (5)
- Inspect the packaging and the blood bag set prior to use. (5)
- The blood bag set is no longer sterile under certain conditions. (5)
- Do not process whole blood less than 2 hours after collection. (5)
- Residual leukocytes are not intended for transfusion. (5)
- Use aseptic technique during blood collection to ensure donor safety and product quality. (5)
- Do not vent the blood bag set. (5)

ADVERSE REACTIONS

To report SUSPECTED ADVERSE REACTIONS, contact Terumo BCT, Inc. at 1-877-339-4228 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. (6)

USE IN SPECIFIC POPULATIONS

The Reveos SELECT set has not been studied in controlled clinical trials with specific populations. (8)

Revised: 3/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

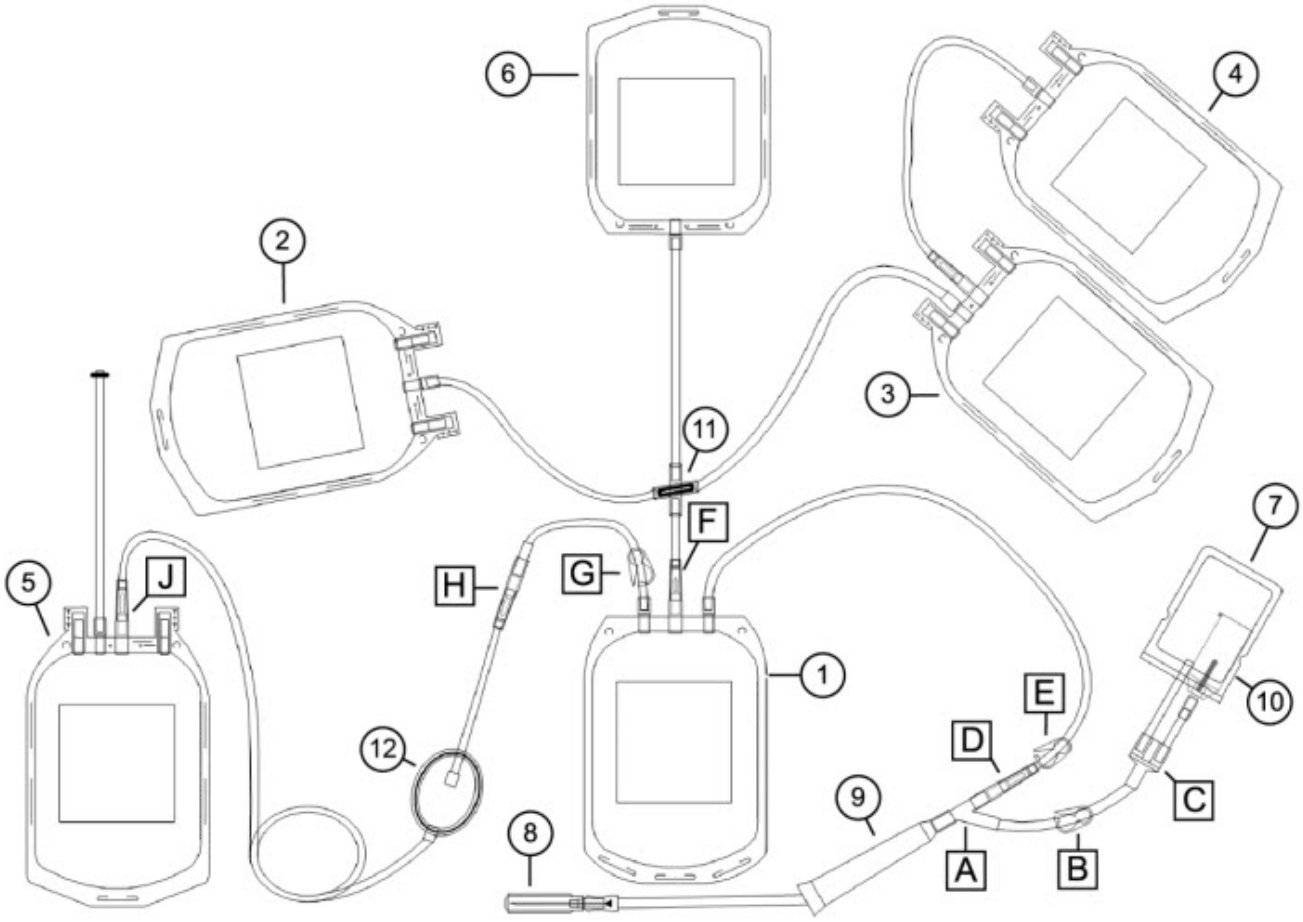
1 INDICATIONS AND USAGE

The Reveos® SELECT set is intended to collect a unit of whole blood and to process the whole blood unit on the Reveos Automated Blood Processing System, producing blood components.

Rx only.

2 DOSAGE AND ADMINISTRATION

Set Diagram



1 Whole blood bag	7 Sample/diversion bag	A, C: Y connector
2 Interim platelet unit (IPU) bag	8 Needle	B, G: Blue clamp
3 Plasma bag	9 Needle injury protector (NIP)	D, F, H, J: CLIKTIP frangible connector
4 Plasma cryoprecipitate reduced bag	10 Sample tube holder/luer adapter	E: White clamp
5 Red blood cell (RBC) bag	11 Cross-connector	
6 Residual leukocyte bag	12 RBC leukoreduction filter	

This document provides blood collection and post-processing instructions specific to the Reveos SELECT set. For warnings, cautions, and instructions on processing whole blood with the Reveos system, see the Reveos system operator's manual.

Note: Refer to the instructions for use provided by the manufacturer of your tubing sealer to ensure that the tubing sealer is appropriate for the tubing on the blood bag set.

Note: You must validate the process for producing, storing, and handling Cryoprecipitated Antihemophilic Factor within your institution's standard operating procedure (SOP), including procedures for using the plasma cryoprecipitate reduced bag.

Blood Collection

Required Supplies:

- Scale and/or blood mixing device
- Tubing sealer
- Evacuated blood collection tubes

1. If it is part of your institution's SOP, make a loose knot in the collection tubing between white clamp E and the whole blood bag.
2. Separate the sample/diversion bag from the other bags.
3. Load the bags onto a scale and/or blood mixing device according to your institution's SOP. Ensure that the whole blood bag and the sample bag are lower than the donor's arm.
4. Close blue clamp B.
5. Apply a blood pressure cuff or a tourniquet to the donor's arm.
6. Prepare the venipuncture site.
7. Twist the needle cap until the resistance stops and then pull the needle cap straight off.
8. Perform the venipuncture according to your institution's SOP.
9. Open blue clamp B.
10. Position the sample/diversion bag with blue clamp B at the top and the sample tube holder/luer adapter at the bottom (see Figure 1). Allow the desired volume of whole blood to flow into the sample/diversion bag. The nominal volume of the sample bag is 60 mL. When the volume reaches the marking, approximately 40 mL has been collected.
11. Close blue clamp B.
12. Break CLIKTIP D to allow the whole blood to flow into the whole blood bag. Bend the CLIKTIP in both directions to ensure that you break it completely.
13. Seal the sample/diversion tubing as near as possible to Y connector A. Seal the tubing according to your institution's SOP.
14. Invert the sample/diversion bag and transfer donor blood samples from the sample/diversion bag, using evacuated blood collection tubes. Transfer samples as soon as possible after venipuncture to avoid possible clot formation in the sample/diversion bag.

    a. Hold the sample/diversion bag and sample tube holder/luer adapter in one hand with blue clamp B positioned at the bottom (see Figure 2).
    b. Using the other hand, insert a blood collection tube firmly into the sample tube holder/luer adapter. After filling the blood collection tube, remove the tube from the sample tube holder. Repeat the process to take additional samples.

15. Mix the whole blood and the anticoagulant during collection according to your institution's SOP.
16. Collect the target volume of blood ± 10%, as specified on the whole blood bag label.
17. Close white clamp E and perform one of the following steps:
    - If you made a knot in the collection tubing in step 1, tighten the knot firmly.
    - If you did not make a knot in step 1, seal the collection tubing near CLIKTIP D.

18. Hold the needle hub and then slide the NIP partially over the needle hub (see Figure 3).
19. Gently pull on the tubing to withdraw the needle from the donor's arm and into the

NIP until the needle locks securely (see Figure 4).

20. Seal the collection tubing near CLIKTIP D if you did not do so in step 17. Disconnect the sealed tubing that includes the needle and the sampling assembly. Dispose of the needle, the NIP, and the sample tube holder safely according to your institution's SOP and/or local regulations.
21. Immediately after collection is complete, invert the whole blood bag several times to thoroughly mix the whole blood and the anticoagulant.
22. If required, strip the blood in the collection tubing into the whole blood bag according to your institution's SOP.
23. Seal and disconnect the collection tubing between 1 in and 2 in (2.5 cm and 5.0 cm) away from the whole blood bag. Dispose of the collection tubing safely according to your institution's SOP and/or local regulations.
24. Place the whole blood unit into a temperature-controlled environment according to your institution's SOP.
25. Pack and transport the whole blood unit to the processing laboratory according to your institution's SOP.

Figure 1: Sample/diversion bag

Figure 2: Collecting a whole blood sample

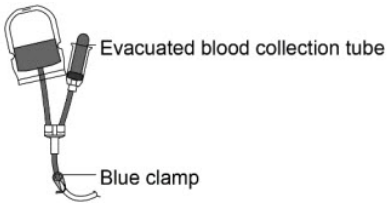


Figure 3: Sliding the NIP over the needle hub

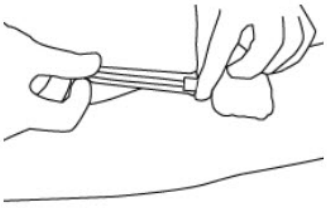
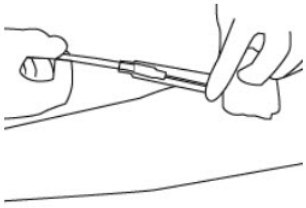


Figure 4: Withdrawing the needle into the NIP



Post-Processing and Red Blood Cell Leukoreduction

Required Supplies:

- Leukoreduction rack
- Tubing sealer

1. After processing, remove the plasma bag, the plasma cryoprecipitate reduced bag, the residual leukocyte bag, and the IPU bag from the organizer and handle them according to your institution's SOP.
   Note: You must rest and agitate the IPU prior to platelet pooling. For conditions for resting and agitating the IPU, see the platelet pooling set instructions for use.
2. Prepare a leukoreduction rack with a head height of at least 43½ in (110 cm).
3. Remove the RBC bag from the organizer.
4. Hang the RBC bag from the leukoreduction rack so that the filter hangs vertically.

5. Open blue clamp G.
6. Break CLIKTIP H.
7. Break CLIKTIP J.
8. Drain all of the additive solution through the filter and into the whole blood bag.
9. Close blue clamp G.
10. Gently mix the additive solution with the RBC unit in the whole blood bag.
11. Hang the whole blood bag on the leukoreduction rack.
12. Ensure that the tubing is free of kinks or other obstructions.
13. Open blue clamp G and allow the mixture of red blood cells and additive solution to flow through the leukoreduction filter.
    Do not squeeze the whole blood bag to increase the draining rate. Filtration is complete when the inlet side of the leukoreduction filter collapses and the red blood cells drain from the inlet side of the filter.
14. Seal the RBC tubing below the leukoreduction filter and disconnect the RBC bag. Ensure that the filter remains in a vertical position while you seal the tubing, as this prevents the loss of red blood cells.
15. Dispose of the whole blood bag and filter assembly safely according to your institution's SOP and/or local regulations.
16. Seal the line for sampling segments according to your institution's SOP.
17. Store the RBC product according to your institution's SOP.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever the solution and container permit.

3 DOSAGE FORMS AND STRENGTHS

70 mL Citrate Phosphate Dextrose (CPD) anticoagulant is a sterile solution in a PVC plasticized with DEHP bag. Each 70 mL of CPD contains: Dextrose (anhydrous) 1.624 g, Trisodium Citrate (dihydrate) 1.841 g, Citric Acid (monohydrate) 0.229 g, Sodium Dihydrogen Phosphate (dihydrate) 0.176 g, and water for injection up to 70 mL.

111 mL Additive Solution 5 (AS-5) red cell preservative solution is a sterile solution in a PVC plasticized with DEHP bag. Each 111 mL of AS-5 contains: Dextrose (anhydrous) 0.908 g, Sodium Chloride 0.973 g, Mannitol 0.583 g, Adenine 0.035 g, and water for injection up to 111 mL.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

- Single-use product. Do not reuse. This product is intended to be single use only and is not intended to be reused or re-sterilized in any manner. Terumo Blood and Cell Technologies cannot ensure the functionality or sterility of the product if it is reused or re-sterilized. Reuse of a single-use disposable set may result in:
  - Product performance issues due to loss of product integrity, including but not limited to the following:
    - Fluid leaks
    - Parts that are warped or deformed

        - Plastics that are brittle and discolored
        - Filters that have reduced filtration capabilities
    - Viral infections such as hepatitis or human immunodeficiency virus (HIV)
    - Bacterial infections
    - Cross-contamination

  Any of these risks could result in serious injury or death. These risks are shared by product users, donors, patients, and recipients of the end product of the device.
- Inspect the packaging and the blood bag set prior to use. Do not use the set if any of the following conditions are present:
    - There are tears or holes in the outer aluminum foil packaging or in the individual transparent packaging wrap.
    - The tubing has severe kinks.
    - The blood bag set is incorrectly assembled.
    - The blood bag set is defective or damaged, or there are any leaks from the fluid-filled components of the set.
    - Any clamps are closed.
    - The needle cap is not in place.
    - The solutions are cloudy or discolored or contain particulates.

  Using the blood bag set under these conditions may result in product contamination or poor performance during collection and/or processing.
  Note: It is normal to have some condensation in the outer aluminum foil pouch and individual transparent packaging wrap due to sterilization.
- The blood bag set is no longer sterile if any of the following conditions occur:
    - You disconnect the sample/diversion bag before you seal the sample/diversion tubing.
    - You remove blood samples before you seal the sample/diversion tubing.
    - The integrity of the set is compromised for any reason.

  Manage the blood bag set according to your institution's SOP.
- Do not process whole blood less than 2 hours after collection. Processing blood too soon after collection may result in incomplete RBC leukoreduction and/or a reduced platelet yield.
- Residual leukocytes are a by-product of the processing procedure and contain mostly white blood cells (WBC), with some plasma, platelets, and red blood cells (RBC). Residual leukocytes are not intended for transfusion.
- Use aseptic technique during blood collection to ensure donor safety and product quality.
- Do not vent the blood bag set.

6. ADVERSE REACTIONS

To report SUSPECTED ADVERSE REACTIONS, contact Terumo BCT, Inc. at 1-877-339-4228 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

8 USE IN SPECIFIC POPULATIONS

The Reveos SELECT set has not been adequately studied in controlled clinical trials with specific populations.

11 DESCRIPTION

The Reveos SELECT set has been evaluated for use with the Reveos system.

The blood and fluid pathways of the blood bag set are steam-sterilized and are non-pyrogenic.

The blood bag set is intended for use by appropriately trained phlebotomists who collect whole blood and by blood center personnel who process whole blood using the Reveos system.

The formulas of the active ingredients are provided in Tables 1 and 2.

Table 1: CPD Active Ingredients

Ingredients	**Molecular Formula**	**Molecular Weight**
Dextrose (anhydrous)	$C_6H_{12}O_6$	180.16 g/mol
Trisodium Citrate (dihydrate)	$C_6H_5Na_3O_72H_2O$	294.10 g/mol
Citric Acid (monohydrate)	$C_6H_8O_7H_2O$	210.14 g/mol
Sodium Dihydrogen Phosphate (dihydrate)	$NaH_2PO_42H_2O$	156.01 g/mol
Water for Injection	H_2O	18.02 g/mol

Each 70 mL of CPD contains: Dextrose (anhydrous) 1.624 g, Trisodium Citrate (dihydrate) 1.841 g, Citric Acid (monohydrate) 0.229 g, Sodium Dihydrogen Phosphate (dihydrate) 0.176 g, and water for injection up to 70 mL.

Table 2: AS-5 Active Ingredients

Ingredients	**Molecular Formula**	**Molecular Weight**
Dextrose (anhydrous)	$C_6H_{12}O_6$	180.16 g/ mol
Sodium Chloride	NaCl	58.44 g/mol
Mannitol	$C_6H_{14}O_6$	182.17 g/mol
Adenine	$C_5H_5N_5$	135.13 g/mol
Water for injection	H_2O	18.02 g/mol

Each 111 mL of AS-5 contains: Dextrose (anhydrous) 0.908 g, Sodium Chloride 0.973 g, Mannitol 0.583 g, Adenine 0.035 g, and water for injection up to 111 mL.

The PVC plasticized with DEHP bags are not made with natural rubber latex.

The bags contain materials that have been tested to demonstrate the suitability of the containers for storing pharmaceutical solutions. The bags are nontoxic and biologically inert. The blood bag set is a closed system and is not dependent upon entry of external air during administration. The blood bag set is overwrapped to provide protection from the physical environment and to provide an additional moisture barrier when necessary.

12 CLINICAL PHARMACOLOGY

12.1. Mechanism of Action

CPD Mechanism of Action

CITRATE PHOSPHATE DEXTROSE acts as an extracorporeal anticoagulant by binding the free calcium in the blood. Calcium is a necessary co-factor to several steps in the clotting cascade. The following ingredients are key components of the solution:

- Citric Acid for pH regulation
- Sodium Citrate functions as an anticoagulant
- Dextrose for isotonicity
- Sodium Dihydrogen Phosphate for pH buffering

This solution has no clinical effect in transfused patients.

AS-5 Mechanism of Action

ADDITIVE SOLUTION FORMULA 5 acts to preserve and extend the shelf life of packed RBC products for later transfusion to patients. The following ingredients are key components of the solution:

- Dextrose for RBC nutrition
- Sodium Chloride for isotonicity
- Mannitol to protect RBC membranes
- Adenine to support adenosine triphosphate (ATP) levels

This solution has no clinical effect in transfused patients.

16 HOW SUPPLIED/STORAGE AND HANDLING

The blood bag sets are packaged in outer aluminum foil pouches. Each outer aluminum foil pouch contains 2 blood bag sets. Each case contains 8 outer aluminum foil pouches.

CATALOG NUMBER	NDC NUMBER	
6FO506A0	Carton:	82906-506-16
	Aluminum foil:	82906-506-02
	Primary Collect Bag:	82906-506-01

STORAGE

- Long-term storage temperature: 1 °C to 30 °C
- Permitted temperature excursions:
  - –20 °C to 1 °C for up to 2 weeks
  - Up to 50 °C for up to 1 week

Use blood bag sets within 28 days after you open the outer aluminum foil pouch. To store unused blood bag sets, return them to the outer aluminum foil pouch and reclose the pouch with tape or a clip. Once you open the transparent packing wrap, you must use the blood bag set within 7 days, not exceeding 28 days from when you opened the outer aluminum foil pouch. Each outer aluminum foil pouch contains sachets that absorb oxygen. Dispose of the sachets and the outer aluminum foil pouch with normal waste.

Issued: **February 2023**

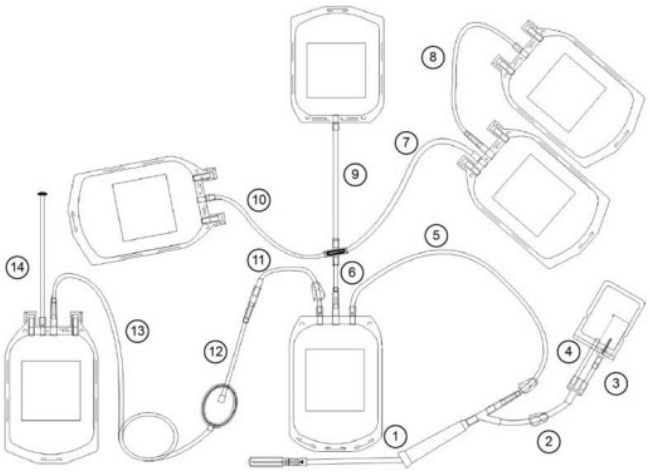
Manufactured by:
TERUMO BCT Vietnam CO., Ltd.
Long Duc Industrial Park, Long Duc Commune,
Long Thanh District, Dong Nai Province, Vietnam

For:
Terumo BCT, Inc.
10811 W. Collins Ave.
Lakewood, CO 80215

RETURN OF USED PRODUCT

If for any reason this product must be returned to Terumo BCT, Inc., a returned goods authorization (an RGA number) is required from Terumo BCT prior to shipping. Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number, may be obtained from the Terumo BCT Quality Assurance Department. **IT IS THE RESPONSIBILITY OF THE HEALTH CARE INSTITUTION TO ADEQUATELY PREPARE AND IDENTIFY THE PRODUCT FOR RETURN SHIPMENT. Please contact your local representative for information regarding returned goods and product complaints.**

Tubing Specifications (non-sterile, nominal* dimensions)



Description	Primary tubing	Sample tube holder/luer adapter tubing
Item(s)	1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14	3
Wall Thickness	0.7 mm	1.3 mm
Outer Diameter	4.4 mm	4.4 mm
Inner Diameter	3.0 mm	1.8 mm

* **Note**: The tubing dimensions listed on this document are nominal values and are intended for use in determining compatibility with various types of laboratory equipment. The nominal values are specified target dimensions; however, because they are based on non-sterile tubing measurements, and due to variations in the manufacturing process, the actual dimensions may be slightly different.

Tubing Set Composition

- Primary tubing: Polyvinyl chloride (PVC) plasticized with Di(2-ethylhexyl)phthalate (DEHP)

- Bags: PVC plasticized with DEHP
- RBC leukoreduction filter: PVC plasticized with DEHP housing, polybutylterephthalate media
- Access needle: Stainless steel (contains cobalt)
- Needle injury protector (NIP): Polypropylene (PP)
- Sample tube holder/luer adapter: PVC/polycarbonate housing, stainless steel needle
- Clamps: Polyacetal
- Cross-connector: PVC

Not made with natural rubber latex.

This product may be covered by one or more patents or pending patent applications.

See TERUMOBCT.COM/patents for details.

Terumo BCT, Inc. ("Terumo Blood and Cell Technologies", "Terumo BCT")

PRINCIPAL DISPLAY PANEL - 70 mL Bag Pouch Case Label

TERUMO Reveos® SELECT

CPD/AS-5 RED CELL PRESERVATIVE SOLUTION FOR COLLECTION OF 500mL OF BLOOD

CAUTIONS:

For single use only. Sterile fluid path, sterilized
using steam. Non-pyrogenic fluid path.

Do not re-sterilize.

Read the instructions carefully before use.

Do not use if package is damaged.

Store between 1°C and 30°C

Manufactured by :

TERUMO BCT Vietnam Co., Ltd.

Long Duc Industrial Park, Long Duc Commune,
Long Thanh District, Dong Nai Province, Vietnam

For :

TERUMO BCT, Inc.

10811 W. Collins ave.
Lakewood, CO 80215

Rx ONLY

D0000036575-A

XXXX

LOT : LOT #

MFG DATE : Date of Mfg.

EXPIRY DATE : Exp. Date

CAT. NO. : 6FO506A0

UNITS : 016

NDC : 82906-506-16

NDC (ISBT 128)

TERUMO **Reveos®** SELECT

CPD/AS-5 RED CELL PRESERVATIVE SOLUTION FOR COLLECTION OF 500mL OF BLOOD

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D0000036575-A

XXXX

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CAT. NO. : 6FO506A0 NDC : 82906-506-16

UNITS : 016

NDC (ISBT 128)

REVEOS SELECT CPD/AS-5 RED CELL PRESERVATIVE FOR COLLECTION OF BLOOD

dextrose monohydrate, trisodium citrate dihydrate, anhydrous citric acid, and sodium phosphate, monobasic, unspecified form solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:82906-506
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextrose Monohydrate (UNII: LX22YL083G) (Anhydrous Dextrose - UNII:5SL0G7R0OK)	Dextrose Monohydrate	1.624 g in 70 mL
Trisodium Citrate Dihydrate (UNII: B22547B95K) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1.841 g in 70 mL
Anhydrous Citric Acid (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	Anhydrous Citric Acid	0.229 g in 70 mL
Sodium Phosphate, Monobasic, Unspecified Form (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	Sodium Phosphate, Monobasic, Unspecified Form	0.176 g in 70 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82906-506-16	16 in 1 CASE		
1	NDC:82906-506-02	2 in 1 POUCH		
1	NDC:82906-506-01	70 mL in 1 BAG; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN880217	08/16/2023	

Labeler - Terumo BCT Vietnam CO., Ltd. (555361198)

Registrant - Terumo BCT, Ltd. (233649834)

Establishment

Name	Address	ID/FEI	Business Operations
Terumo BCT Vietnam CO., Ltd.		555361198	LABEL(82906-506) , ANALYSIS(82906-506) , STERILIZE(82906-506) , MANUFACTURE(82906-506)

Revised: 8/2023

Terumo BCT Vietnam CO., Ltd.