TERUFLEX BLOOD BAG SYSTEM ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) AND OPTISOL RED CELL PRESERVATIVE - anticoagulant citrate phosphate dextrose (cpd) and as-5 red cell preservative
Terumo Corporation

TERUFLEX® BLOOD BAG SYSTEM CPD/OPTISOL® SOLUTION BLOOD BAG SYSTEM

Revised 8/96

TERUFLEX® BLOOD BAG SYSTEM
CPD/OPTISOL® SOLUTION

Read these instructions before use.

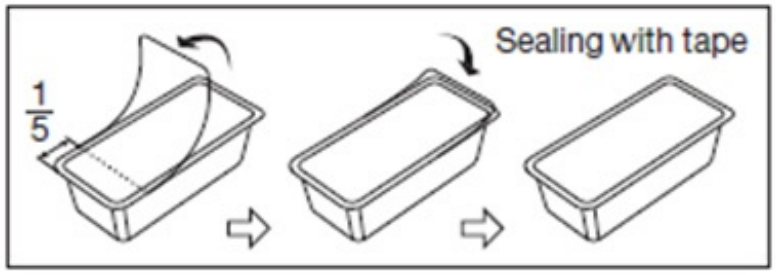
INSTRUCTIONS FOR BLOOD COLLECTION: Use aseptic technique
1. Confirm that all numbered tubing of each blood bag unit contains segment numbers.
2. Make a loose knot in the donor tubing approximately 10 cm from needle unless alternate methods are used to seal tubing.
3. Clamp donor tubing.
4. Suspend primary bag as far as possible below the donor's arm.
5. Apply blood pressure cuff or tourniquiet to donor's arm. Disinfect site of phlebotomy. If blood pressure cuff is used, inflate cuff to 60 mmHg.
6. Remove needle protector and perform phlebotomy. Remove clamp to permit blood flow into primary bag.
CAUTION Do not touch needle after removing the needle protector.
7. Appropriately secure donor tubing to donor's arm.
8. MIX BLOOD WITH ANTICOAGULANT AT SEVERAL INTERVALS DURING COLLECTION.
9. Collect labeled volume of blood (+/- 10%).
10. Tighten knot firmly after collection. Clamp between knot and needle. Sever donor tubing between knot and clamp. Collect blood samples.
11. Reapply clamp to donor tubing; release pressure on donor's arm and remove needle. Seal donor tubing.
CAUTION Discard tubing/phlebotomy needle unit according to institutional procedures.
12. Immediately after collection, invert bag several times to assure blood and anticoagulant are well mixed.
13. Strip blood from donor tubing into bag, mix well, and allow tubing to refill. Seal on or near X marks on donor tubing to provide numbered aliquots of anticoagulated blood for testing.
14. Centrifuge unit to separate red cells from plasma.
15.The time of addition of OPTISOL Solution may vary depending on the processing option selected. Add solution under one of the following conditions.
a) After removal of plasma from freshly collected blood.
b) Within 8 hours of blood collection if components are prepared.
c) Within 72 hours of collection if blood is refrigerated immediately following collection.
16. Snap CLIKTIP (incline closure device) of primary collection bag and transfer plasma into satellite bag. Clamp transfer tubing of satellite bag.
17. Snap CLIKTIP of OPTISOL Solution bag and drain contents into primary bag containing red blood cells. Seal tubing of primary bag in two places, and cut between seals and separate from satellite bag(s). NOTE: For TERUFLEX double bags, seal OPTISOL Solution bag tubing in two places, and cut between seals. Discard OPTISOL Solution container.
18. Invert the red cell- OPTISOL mixture several times to insure that the final AS-5 red cell product is well suspended.
19. Store AS-5 Red Blood Cells between 1-6^{o}C.

20. Infuse AS-5 Red Blood Cells within 42 days of collection.

For further processing, use standard component processing techniques.

To open the blister package, peel the cover film back 4/5 of its length.

After opening, unused bags may be stored for 30 days by returning cover film to original position and sealing with tape to prevent possible loss of moisture.



CAUTIONS
• THE PACKET OF AGELESS CONTAINED IN THIS PACKAGE ABSORBS OXYGEN AND GENERATES HEAT ON REMOVAL AND SHOULD BE HANDLED WITH CARE.
• DISPOSE WITH PACKET IN TRAY.
• DO NOT DISPOSE WITH WASTES CONTAINING VOLATILE OR FLAMMABLE MATERIALS.
• DISCARD AGELESS PACKET WITHOUT OPENING.

TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-Ku, Tokyo, Japan
®: Registered Trademark

N-BB-OP-A (4)

Tray/Case Label

TERUFLEX® BLOOD BAG SYSTEM

CPD WITH OPTISOL® RED CELL PRESERVATIVE SOLUTION FOR COLLECTION OF 450mL OF BLOOD

Each unit consists of a primary bag containing 63mL of Anticoagulant CPD solution, with a satellite bag containing 100mL of OPTISOL Red Cell Preservative Solution.

Each 63mL Anticoagulant CPD solution USP contains 1.61g Dextrose (monohydrate) USP, 1.66g Sodium Citrate (dihydrate) USP,188mg Citric Acid (anhydrous) USP, 144mg Monobasic Sodium Phosphate (monohydrate) USP.

Each 100mL OPTISOL Red Cell Preservative Solution contains 877mg

Sodium Chloride USP, 900mg Dextrose (monohydrate) USP, 525mg
Mannitol USP, 30mg Adenine USP.

STERILE, NON-PYROGENIC FLUID PATH.
DO NOT USE UNLESS ANTICOAGULANT IS CLEAR

CODE

LOT No.

EXPIRY

UNITS

DONOR NEEDLE 16G x 1 1/2″ (1.60 x 38mm)
Rx ONLY
RECOMMENDED STORAGE: Room Temperature (15-30°C/59-86°F).
Avoid excessive heat. Protect from freezing.

After opening, unused bags may be stored for 30 days by returning cover film to original position and sealing with tape to prevent possible loss of moisture. See Instructions For Blood Collection.

Manufactured by : **TERUMO CORPORATION** Tokyo, Japan
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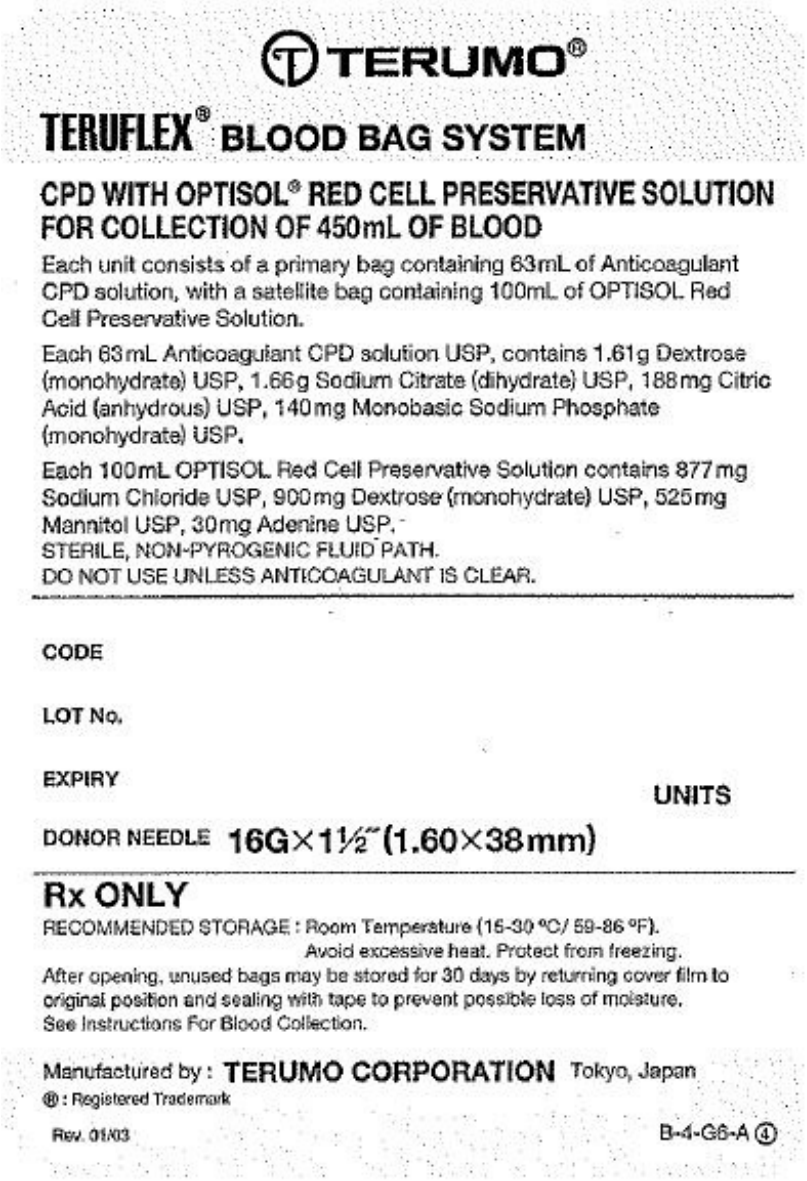
B-4-G6-A (4)



TERUFLEX BLOOD BAG SYSTEM ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) AND OPTISOL RED CELL PRESERVATIVE

anticoagulant citrate phosphate dextrose (cpd) and as-5 red cell preservative kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53877-005

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53877-005-21	24 in 1 CASE		
1		1 in 1 BAG		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BAG	63 mL
Part 2	1 BAG	100 mL

Part 1 of 2

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD)

anticoagulant citrate phosphate dextrose (cpd) solution

Product Information	
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Trisodium Citrate Dihydrate (UNII: B22547B95K) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	26.3 g in 1000 mL
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) (Phosphate Ion - UNII:NK08V8K8HR, Sodium Cation - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM	2.22 g in 1000 mL
Dextrose Monohydrate (UNII: LX22YL083G) (Anhydrous Dextrose - UNII:5SL0G7R0OK)	Dextrose Monohydrate	25.5 g in 1000 mL
Anhydrous Citric Acid (UNII: XF417D3PSL) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	2.99 g in 1000 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		63 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	01/13/2010	

Part 2 of 2

OPTISOL RED CELL PRESERVATIVE

as-5 red cell preservative solution

Product Information

Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Chloride (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	Sodium Chloride	877 mg in 100 mL
Dextrose Monohydrate (UNII: LX22YL083G) (Anhydrous Dextrose - UNII:5SL0G7R0OK)	Dextrose Monohydrate	900 mg in 100 mL
Mannitol (UNII: 3OWL53L36A) (Mannitol - UNII:3OWL53L36A)	Mannitol	525 mg in 100 mL
Adenine (UNII: JAC85A2161) (Adenine - UNII:JAC85A2161)	Adenine	30 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		100 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	01/13/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN880217	01/13/2010	

Labeler - Terumo Corporation (690543319)

Establishment

Name	Address	ID/FEI	Business Operations
Terumo Corp. - Fujinomiya Factory		695214015	MANUFACTURE(53877-005) , STERILIZE(53877-005) , ANALYSIS(53877-005) , LABEL(53877-005)