

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

TERUFLEX® BLOOD BAG SYSTEM WITH BLOOD SAMPLING ARM® CPD/OPTISOL® SOLUTION

Issued 8/96

TERUFLEX® BLOOD BAG SYSTEM With Blood Sampling Arm® CPD/OPTISOL® SOLUTION

Read these instructions carefully before use.

INSTRUCTIONS FOR BLOOD COLLECTION: Use aseptic technique

Materials Needed:

VENOJECT® II Tube Holder (code P-1316R)

VENOJECT® II Multi-Sample Luer Adapter (code MN *2000)

VENOJECT® II Plastic Blood Collection Tubes (or equivalent glass or plastic evacuated blood collection tube)

1. Confirm that all numbered tubing of each blood bag unit contains segment numbers.
2. Make a loose knot in donor tubing below "Y" 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 tourniquet to donor's arm. Disinfect site of phlebotomy. If blood pressure cuff is used, inflate cuff to approximately 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 "Y". Sever donor tubing between the knot and clamp. Alternate methods may be used to seal tubing.

CAUTION Do not use the dielectric tube sealer while the needle is connected to the donor's body. Anytime before Step #13 below, sever donor tubing between the two seals.

Collect blood samples as follows:

a) Connect VENOJECT II Multi-Sample Luer Adapter to VENOJECT II Tube Holder (Fig. 1).

b) Remove covers and connect multi-sample luer adapter to female luer at end of donor sampling tubing (Fig. 2).

c) Snap CLIKTIP in donor sampling tubing to open blood pathway.

Insert Fig. 1 here

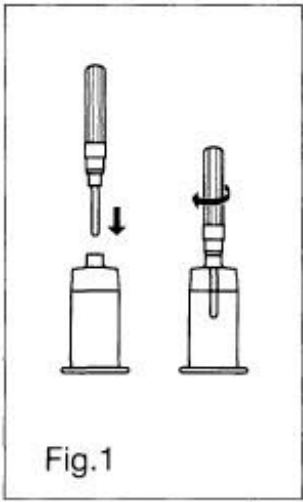
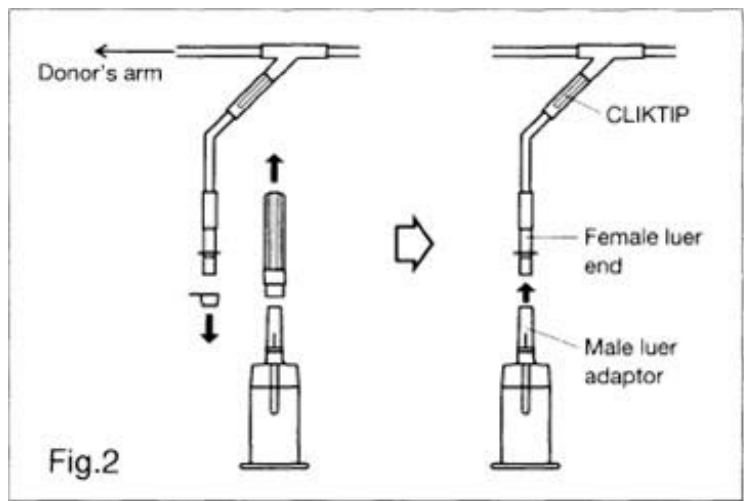


Fig.1

Insert Fig. 2 here



d) Insert blood collection tube (VENOJECT II or equivalent) firmly into VENOJECT II Tube Holder : when full, remove sample tube from holder. Repeat to collect additional samples.

11. Reapply clamp to donor tubing between phlebotomy needle and "Y"; release pressure on donor's arm and remove needle.

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 the 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. The time of addition of OPTISOL Solution may vary depending on the processing option selected. Add the 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.

15. Centrifuge the unit to separate red cells from plasma.

16. Snap CLIKTIP (inline 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 the final AS-5 red cell product is well suspended.

19. Store AS-5 Red Blood Cells between 1-6°C.

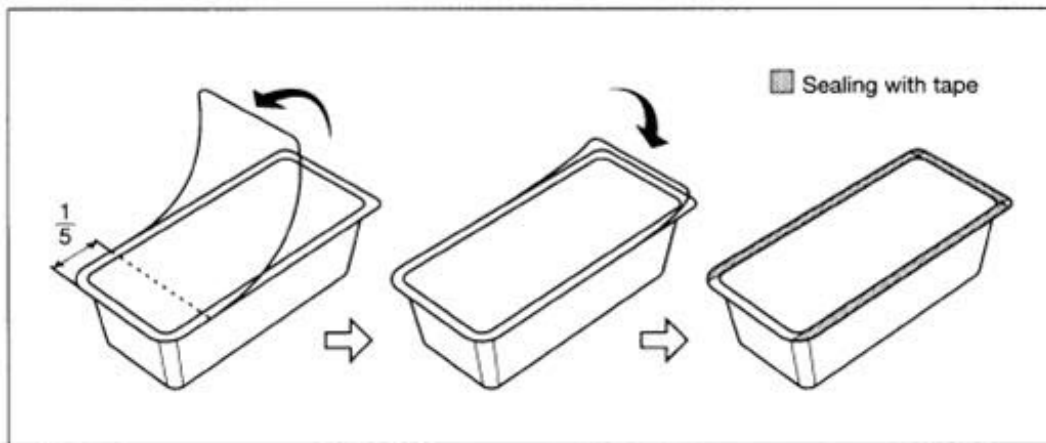
20. Infuse AS-5 Red Blood Cells within 42 days of collection.

For further processing, use standard component processing techniques.

To open blister package, peel cover film back four fifths 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.

Insert Fig. 3 here



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® TERUMO CORPORATION 44-1, 2-CHOME, HATAGAYA, SHIBUYA-KU,
TOKYO, JAPAN

®: Registered Trademark

N-BB-OP-A(SP) 3

Tray/Case Label

**TERUFLEX® BLOOD BAG SYSTEM with
BLOOD SAMPLING ARM®**

**CPD WITH OPTISOL® RED CELL PRESERVATIVE SOLUTION
FOR COLLECTION OF 500mL OF BLOOD**

Each unit consists of a collection bag containing 70mL of Anticoagulant CPD solution, with a satellite bag containing 111mL of OPTISOL Red Cell Preservative Solution.

Each 70mL Anticoagulant CPD solution USP contains 1.79g Dextrose (monohydrate) USP, 1.84g Sodium Citrate (dihydrate) USP, 209mg Citric Acid (anhydrous) USP, 156mg Monobasic Sodium Phosphate (monohydrate) USP.

Each 111mL OPTISOL Red Cell Preservative Solution contains 974mg Sodium Chloride USP, 1.00g Dextrose (monohydrate) USP, 583mg Mannitol USP, 33.3mg 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
® : Registered Trademark
Blood Sampling Arm is a trademark of TERUMO CORPORATION.

Rev. 01/03
B-4-H6-A4 2
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TERUFLEX[®] BLOOD BAG SYSTEM with Blood Sampling Arm[™]

CPD WITH OPTISOL[®] RED CELL PRESERVATIVE SOLUTION FOR COLLECTION OF 500mL OF BLOOD

Each unit consists of a primary bag containing 70 mL of Anticoagulant CPD solution, with a satellite bag containing 111 mL of OPTISOL Red Cell Preservative Solution.

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Each 111 mL OPTISOL Red Cell Preservative Solution contains 974 mg Sodium Chloride USP, 1.00 g Dextrose (monohydrate) USP, 583 mg Mannitol USP, 33.3 mg Adenine USP.

STERILE, NON-PYROGENIC FLUID PATH.

DO NOT USE UNLESS ANTICOAGULANT IS CLEAR.

CODE

LOT No.

EXPIRY

UNITS

DONOR NEEDLE **16G×1½" (1.60×38mm)**

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

® : Registered Trademark Blood Sampling Arm is a trademark of TERUMO CORPORATION.

Rev. 01/03

B-4-H6-A4 ②

TERUFLEX BLOOD BAG SYSTEM WITH BLOOD SAMPLING ARM ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) AND OPTISOL (AS-5) 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:53877-009
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53877-009-41	24 in 1 CASE		
1		1 in 1 BAG		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BAG	70 mL
Part 2	1 BAG	111 mL

Part 1 of 2

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD)

anticoagulant citrate phosphate dextrose (cpd) solution

Product Information

Route of Administration	INTRAVENOUS
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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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	05/05/2010	

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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		111 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
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NDA	BN880217	05/05/2010	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN880217	05/05/2010	

Labeler - Terumo Corporation (690543319)

Establishment

Name	Address	ID/FEI	Business Operations
Terumo Corp. - Fujinomiya Factory		695214015	manufacture(53877-009) , STERILIZE(53877-009) , ANALYSIS(53877-009) , LABEL(53877-009)

Revised: 12/2018

Terumo Corporation