

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

Issued 6/03

**TERUFLEX® BLOOD BAG SYSTEM With DIVERSION BLOOD SAMPLING ARM®
CPD/OPTISOL® SOLUTION**

Read these instructions carefully before use. Rx ONLY.

The Diversion Blood Sampling Arm™ is intended to divert and collect blood for obtaining donor test samples.

- For single use only. Sterile and non-pyrogenic fluid path. Sterilized by steam.
- Intended for the collection, processing and preservation of human blood and components.

PRECAUTIONS

- Do not use unless the solutions are clear.
- Avoid excessive heat and direct sunlight. Protect from freezing.
- Recommended storage conditions: Room Temperature (15-30°C/59-86°F).
- The blood bag configuration is specified on the blister pack label.

CAUTION Do not use a dielectric tube sealer to seal the tubing while the needle is connected to the donor's body unless it is approved for such a purpose.

INSTRUCTIONS FOR BLOOD COLLECTION: Use aseptic technique

Materials Needed:

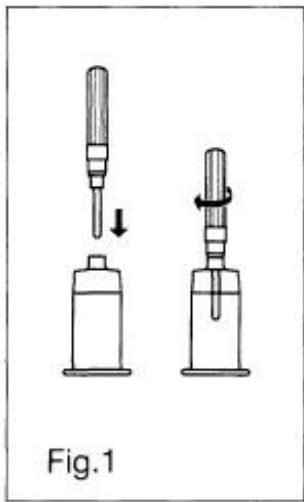
VENOJECT® II Tube Holder (code P-1316R) or equivalent

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

Evacuated Blood Collection Tubes (glass or plastic)

1. Prepare the blood bag following your institution's standard operating procedures.
2. If applicable, make a loose knot in the donor tubing below the "Y" and CLIKTIP™ (inline closure device) unless alternate methods are used to seal the tubing at the end of collection.
3. Temporarily clamp the donor tubing between the phlebotomy needle and the "Y".
- 4. Close the White Clamp below the diversion pouch.**
5. Tube Holder/Luer Adapter Assembly:
 - a) Connect the VENOJECT II Multi-Sample Luer Adapter to the VENOJECT II Tube Holder (or equivalent) (Fig.1).

Insert Fig. 1 here

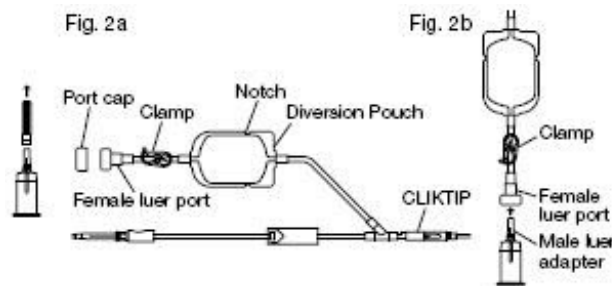


b) Twist and snap to remove the blue port cap at the end of the Diversion Blood sampling Arm (Fig. 2a).

c) Connect the multi-sample luer adapter to the female luer port. (Fig. 2b)

NOTE: Alternatively, steps a, b and c (above) may be performed at any time during bag preparation or after the blood is collected into the diversion pouch.

Insert Fig. 2a and 2b here



6. Suspend the collection bag as far as possible below the donor's arm.
 7. Apply blood pressure cuff or tourniquet to donor's arm. Disinfect site of phlebotomy. If blood pressure cuff is used, inflate to approximately 60 mmHg.
 8. Remove the needle cover and perform phlebotomy. Remove the temporary clamp on the donor tubing to permit blood flow into the Diversion Blood Sampling Arm pouch.
- CAUTION** Do not touch the needle after removing the needle protector. Assure that the White Clamp below the pouch is closed prior to initiating phlebotomy.
9. If using a needle safety device, follow the manufacturer's instructions to secure the device in place.
 10. Appropriately secure donor tubing to donor's arm.
 11. Position the diversion pouch with the notches up and the Tube Holder/Luer Adapter assembly (or port cap) down. When the level of blood in the pouch is approximately in line with the notches, the diversion pouch is full. (Fig. 3a)

NOTE: The approximate fill volume of the pouch at the notches is 35 mL.

12. Permanently seal the tubing between the "Y" and the diversion pouch to maintain a closed system using an aluminum clip or a tube sealer approved for use with tubing connected to a donor. (Fig. 3b)

13. To initiate blood flow into the collection bag, break the CLIKTIP between the "Y" and the primary bag.

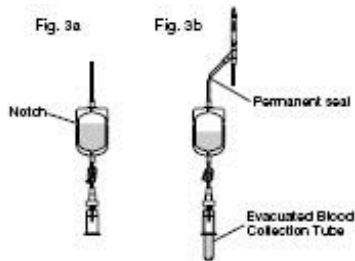
14. To avoid clot formation, collect samples as soon as possible from the diversion pouch as follows (Fig. 3b)

CAUTION Do not collect donor test samples until the tubing between the "Y" and the diversion pouch is permanently sealed.

- a) Open the White Clamp on the tubing below the pouch to open the pathway for sampling.
- b) Position the diversion pouch with the notches up and the Tube Holder/Luer Adapter assembly down. Assure that any air in the pouch is at the top and will not enter the blood collection tubes.
- c) Insert vacuum blood collection tube firmly into the tube holder; when full, remove sample tube from holder. Repeat to collect additional samples.

NOTE: The pouch may be removed after the donor test samples are collected. A second seal must be made between the diversion pouch and the permanent seal prior to removing the pouch.

Insert Fig. 3a and 3b here



15. Once samples are obtained, mix blood with anticoagulant in the primary bag and continue to mix at several intervals during collection.

16. Collect labeled volume of blood (+/-10%).

17. When the desired amount of blood has been collected, seal the tubing or tighten the loose knot (white knot) prepared in step 2. Make a second seal between the first seal or knot and the CLIKTIP below the "Y". Various methods may be used to seal tubing.

18. Release pressure on the donor's arm and remove the needle. If using a needle safety device, follow the manufacturer's instructions to remove the needle. Sever the donor tubing between the two seals previously made below the CLIKTIP and "Y".

CAUTION Discard the Diversion Blood Sampling Arm and phlebotomy needle/donor tubing according to institutional procedures.

19. Immediately after collection, invert the bag several times to assure blood and anticoagulant are well mixed.

20. Strip blood from the donor tubing into the bag, mix well, and allow tubing to refill. Seal on or near the X marks on the donor tubing to provide numbered aliquots of anticoagulated blood for testing.

21. The time of addition of OPTISOL Solution may vary depending on the processing option selected. Add the solution under one of the following conditions after removal of plasma:

a) Within 8 hours of whole blood collection, if components are prepared.

b) Within 72 hours of collection if whole blood is refrigerated immediately following collection.

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

23. Break the CLIKTIP of primary collection bag and transfer the plasma into the satellite bag. Clamp transfer tubing of satellite bag.

24. Break the 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.

25. Invert the red cell- OPTISOL mixture several times to insure the final AS-5 red cell product is well suspended.

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

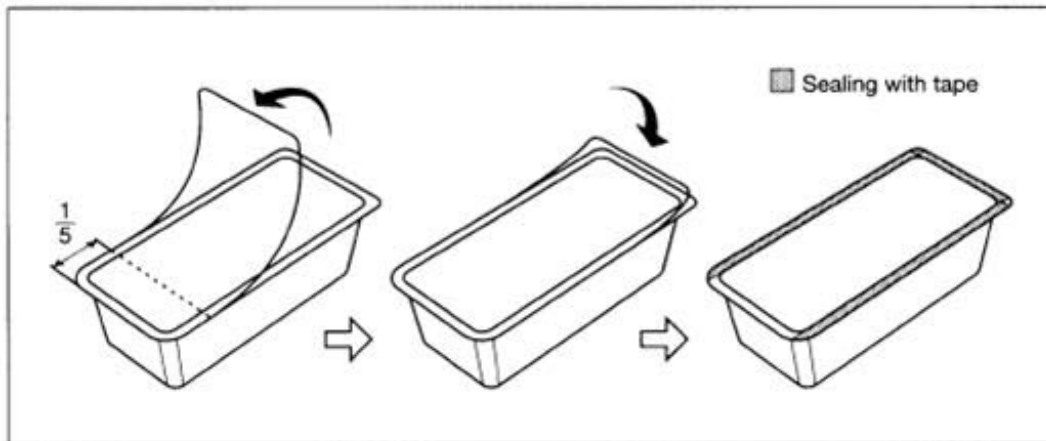
27. Infuse AS-5 Red Blood Cells within 42 days of collection.

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. 4 here



CAUTIONS

- The packet of AGELESS contained in this package absorbs oxygen and generates heat on removal. Handle it with care.
- Dispose with packet in tray.
- Do not dispose with wastes containing volatile or flammable materials.
- Discard AGELESS packet without opening.

N-BB-OP-A2(DB) 1

TERUMO® MANUFACTURED BY: **TERUMO CORPORATION** 44-1, 2-CHOME,
HATAGAYA, SHIBUYA-KU, TOKYO, JAPAN MADE IN JAPAN

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Tray/Case Label

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

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

Each unit consists of a collection 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, 140mg 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
® : Registered Trademark
Diversion Blood Sampling Arm is a trademark of TERUMO CORPORATION.

Issued 05/03
B-4-G6-A2 1
Place Label here



TERUFLEX® BLOOD BAG SYSTEM with Diversion Blood Sampling Arm™

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.

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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×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
Diversion Blood Sampling Arm is a trademark of TERUMO CORPORATION.

Issued 05/03

B-4-G6-A2 ①

TERUFLEX BLOOD BAG SYSTEM WITH DIVERSION 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:53877-008
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53877-008-81	18 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
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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		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	05/05/2010	

Part 2 of 2**OPTISOL RED CELL PRESERVATIVE**

as-5 red cell preservative solution

Product Information

Route of Administration	INTRAVENOUS
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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		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
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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(53877-008) , STERILIZE(53877-008) , ANALYSIS(53877-008) , LABEL(53877-008)

Revised: 12/2018

Terumo Corporation