TERUFLEX BLOOD BAG SYSTEM ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE (CPDA-1) - anticoagulant citrate phosphate dextrose adenine (cpda-1) solution
Terumo Corporation

TERUFLEX® BLOOD BAG SYSTEM
CPDA-1 SOLUTION

For the collection of 250 mL of Whole Blood

Revised 2015-12 N-BB-A 3

FULL PRESCRIBING INFORMATION
*****Sections or subsections omitted from the Full Prescribing Information are not listed [includes sections 4, 6, 7, 8, 9, 10, 12, 13, 14, 15 and 17].

1. INDICATIONS AND USAGE

1.1. Read these instructions carefully before use.
1.2. Rx ONLY.
1.3. Intended for the collection, processing and preservation of Whole Blood and blood components. Not intended for direct intravenous infusion.
1.4. For the collection of 250 mL ±10% Whole Blood:
1.4.1. From elderly, pediatric, or smaller autologous donors who may not tolerate larger blood collections.
1.4.2. For blood collections as directed by a patient's physician.
1.5. **NOTE**: Production of Platelets and Plasma is not intended with this product.

2. DOSAGE AND ADMINISTRATION

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

2.2. Prepare the blood bag following your institution's standard operating procedures.

2.3. Make a loose knot in the donor tubing approximately 10 cm or 4 inches from the needle unless alternate methods are used to seal the tubing at the end of collection.

2.4. Temporarily clamp donor tubing.

2.5. Suspend the collection bag as far as possible below the donor's arm.

2.6. Apply blood pressure cuff or tourniquet to donor's arm. Disinfect site of phlebotomy according to institutional standard operating procedures. If blood pressure cuff is used, inflate to approximately 60 mmHg.

2.7. Remove the needle cover and perform phlebotomy.

2.7.1. **CAUTION**: Do not touch the needle after removing the needle cover.

2.8. Remove the temporary clamp on the donor tubing to permit blood flow into the collection bag.

2.9. Secure donor tubing to donor's arm.

2.10. Mix blood with anticoagulant in the collection bag and continue to mix at several intervals during collection and immediately after collection. If using an automated mixer, follow manufacturer's instructions.

2.11. Collect labeled volume of blood 250 mL ±10%.

2.12. When the desired amount of blood has been collected, seal the tubing or tighten the loose knot

(white knot) prepared in Step 2.3. Temporarily clamp between the knot and needle. Sever donor tubing between knot and clamp. Alternate methods may be used to seal tubing. Collect blood samples using careful attention to aseptic technique and following your institution's standard operating procedures.

2.12.1. **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.

2.13. Reapply clamp to donor tubing; release pressure on donor's arm and remove needle. If using a needle safety device, follow manufacturer's instructions.

2.13.1. **CAUTION**: Discard phlebotomy needle/donor tubing according to institutional standard operating procedures.

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

2.15. Strip blood from donor tubing into collection bag, mix well, and allow tubing to refill; repeat once. To prevent the blood from clotting in the tubing, work quickly as possible. Make an appropriate number of segments of anticoagulated blood for testing by sealing on or near the X marks. Leave segments attached to Whole Blood unit.

2.16. Store CPDA-1 Whole Blood (or Red Blood Cells) between 1 – 6 ° C for up to 35 days.

2.17. For further preparation and processing of other components, use standard processing and storage techniques following approved regulations and standards.

2.17.1. **NOTE**: Production of Platelets and Plasma is not intended with this product.

3. DOSAGE FORMS AND STRENGTHS

3.1. 35 mL Citrate Phosphate Dextrose Adenine (CPDA-1) anticoagulant USP for collection of 250 mL Whole Blood. Each 35 mL contains 105mg Citric Acid (anhydrous) USP, 921mg Sodium Citrate (dihydrate) USP, 77.7mg Monobasic Sodium Phosphate (monohydrate) USP, 1.12g Dextrose (monohydrate) USP and 9.63mg Adenine USP.

5. WARNINGS AND PRECAUTIONS

5.1. Rx ONLY.

5.2. Do not use unless solutions are clear and free from particulates.

5.3. Always inspect the blood bag set for leaks before use.

5.4. Avoid excessive heat and direct sunlight. Protect from freezing.

5.5. Recommended storage conditions: Room Temperature (15-30°C/59-86°F).

5.6. It is normal to have condensation in the blister packaging. If the amount of moisture is greater than expected, check for leaks from the fluid-filled components of the blood bag set.

5.7. Use aseptic techniques.

5.8. 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.

5.9. Do not touch needle after removing the needle cover.

5.10. Discard phlebotomy needle/donor tubing according to institutional standard operating procedures.

5.11. The AGELESS® (oxygen absorber packet, Mitsubishi Gas Chemical) contained in this package absorbs oxygen and generates heat on removal. Do not open and handle it with care.

5.12. Dispose of the AGELESS packet with the blister tray.

5.13. Do not dispose the AGELESS packet with wastes containing volatile or flammable materials.

5.14. Due to possible exposure to infectious agents in the handling of blood, take adequate precautions at all times to prevent exposure to and transmission of such agents. Follow your institution's standard operating procedures.

11. DESCRIPTION

11.1. This blood bag system includes a 16 gauge x 1 1/2 inch (1.60 x 38 mm) needle with needle cover and a 250 mL (nominal capacity 300 mL) collection bag containing 35 mL Citrate Phosphate Dextrose Adenine (CPDA-1) anticoagulant.

11.2. The blood bag collection set is made of PVC (polyvinyl chloride with DEHP plasticizer).

11.3. The blood bag has no components made of natural rubber latex.

11.4. Tubing internal diameter (ID) nominal 3.0 mm.

11.5. Tubing outer diameter (OD) nominal 4.4 mm.

11.6. Donor tubing line maximum 12 segments available.

16. HOW SUPPLIED/STORAGE AND HANDLING

16.1. Single use only.

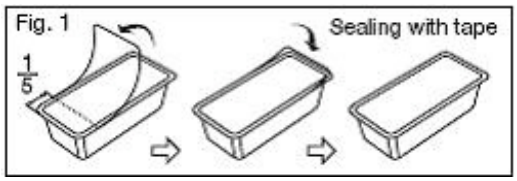
16.2. Sterile and non-pyrogenic fluid path. Sterilized by steam. Opacity of the blood bag system may be observed. This is due to moisture absorption during the sterilization process. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually.

16.3. A Material Safety Data Sheet (MSDS) is not required for this product.

16.4. Recommended storage conditions: Room Temperature (15-30°C/59-86°F).

16.5. Avoid excessive heat and direct sunlight. Protect from freezing.

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



16.7. After opening the blister package, unused blood bags may be stored at room temperature for 96 hours or they may be stored for 30 days by returning cover film to original position and sealing with tape to prevent evaporation of solutions.

16.8. Blood bags in the unopened blister package may be used through the last day of the month and year as indicated on the original manufacturer's packaging.

16.9. The AGELESS packet contained in this package absorbs oxygen and generates heat on removal. Do not open and handle it with care.

16.10. Dispose of the AGELESS packet with the blister tray.

16.11. Do not dispose the AGELESS packet with wastes containing volatile or flammable materials.

16.12. The Single blood bag set, Code **BB□SCD256A**, is supplied 90/case.

MANUFACTURED BY: **TERUMO CORPORATION**

44-1, 2-CHOME, HATAGAYA, SHIBUYA-KU, TOKYO 151-0072, JAPAN MADE IN JAPAN
□R□: Registered Trademark

AGELESS is a registered trademark of MITSUBISHI GAS CHEMICAL CO., INC.

Tray/Case Label
TERUFLEX® BLOOD BAG SYSTEM

ANTICOAGULANT CITRATE PHOSPHATE
DEXTROSE ADENINE SOLUTION (CPDA-1) USP
FOR COLLECTION OF 250mL OF BLOOD

Each unit consists of a primary bag containing 35 mL of solution with 105 mg Citric Acid (anhydrous) USP, 921 mg Sodium Citrate (dihydrate) USP, 77.7 mg Monobasic Sodium Phosphate (monohydrate) USP, 1.12 g Dextrose (monohydrate) USP, 9.63 mg Adenine USP.

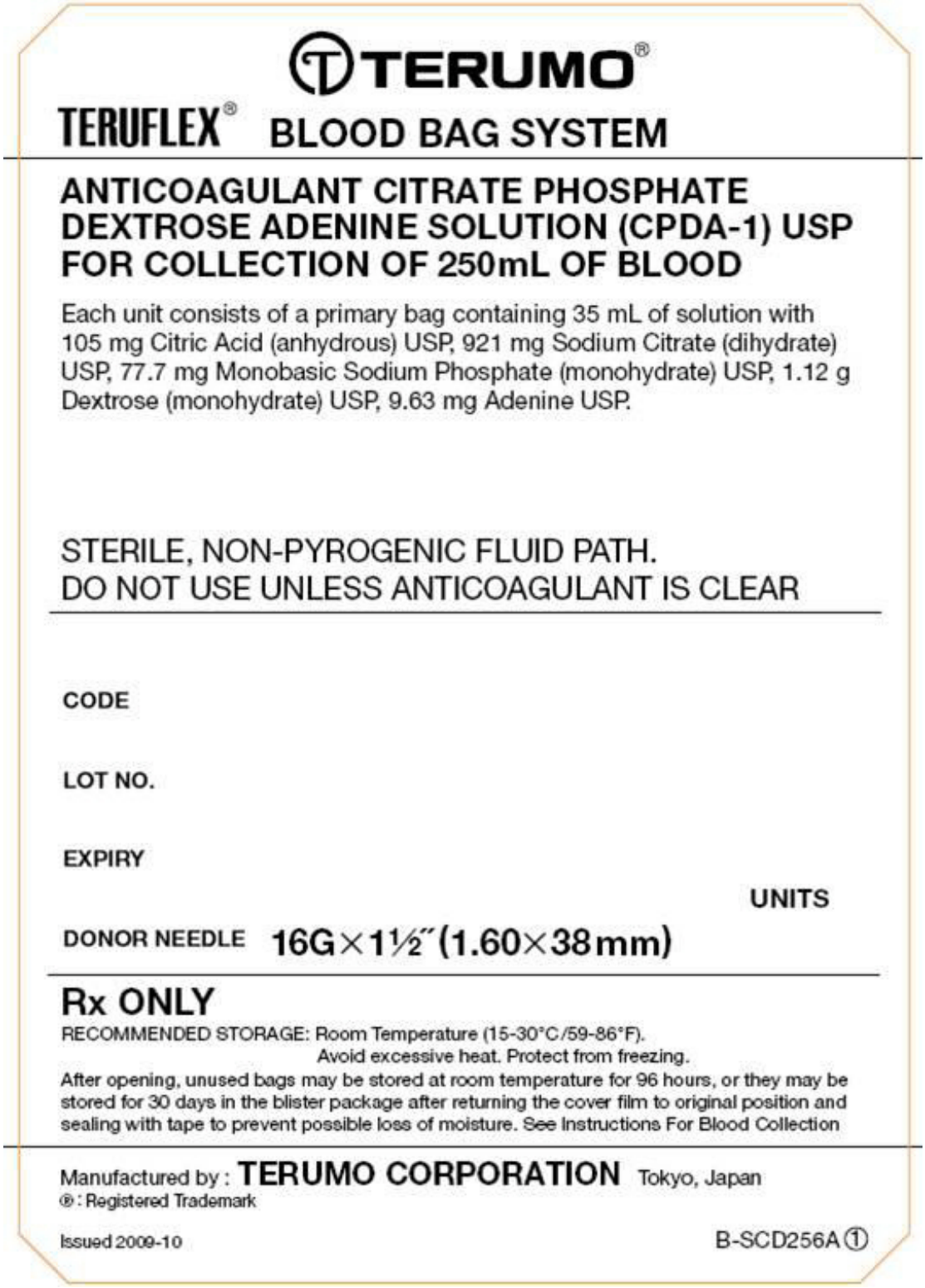
STERILE, NON-PYROGENIC FLUID PATH.
DO NOT USE UNLESS ANTICOAGULANT IS CLEAR

CODE
LOT No.
EXPIRY
UNIT(S)
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 at room temperature for 96 hours, or they may be stored for 30 days in the blister package after returning the 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
Issued 2009 -10

Image of Label:



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anticoagulant citrate phosphate dextrose adenine (cpda-1) solution

Product Information			

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53877-001
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Anhydrous Citric Acid (UNII: XF417D3PSL) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	2.99 g in 1000 mL
Trisodium Citrate Dihydrate (UNII: B22547B95K) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	26.3 g in 1000 mL
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	2.22 g in 1000 mL
Dextrose Monohydrate (UNII: LX22YL083G) (Anhydrous Dextrose - UNII:5SL0G7R0OK)	Dextrose Monohydrate	31.9 g in 1000 mL
Adenine (UNII: JAC85A2161) (Adenine - UNII:JAC85A2161)	Adenine	0.275 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53877-001-01	30 in 1 CASE		
1		35 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	BN820528	11/18/2009	

Labeler - Terumo Corporation (690543319)

Establishment

Name	Address	ID/FEI	Business Operations
Terumo Corp. - Fujinomiya Factory		695214015	MANUFACTURE(53877-001) , PACK(53877-001) , STERILIZE(53877-001) , ANALYSIS(53877-001)

Revised: 12/2018 Terumo Corporation