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
with Blood Sampling Arm®

Revised 2015-12
N-BB-CA-A(SP) 5

CPDA-1 SOLUTION
For the collection of 450 mL or 500 mL of
Whole Blood

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 450 mL ±10% or 500 mL ±10% Whole Blood.
1.5. Integral Blood Sampling Arm for obtaining donor samples for laboratory testing after collection of the Whole Blood unit.
1.6. For further processing, use standard component processing techniques.

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.

2.2.1. Materials Needed:

- VENOJECT®@Tube Holder (code P-1316R) or equivalent
- VENOJECT@Multi-Sample Luer Adapter (code MN*2000T) or equivalent
- Evacuated blood collection tubes (glass or plastic)

2.3. Make a loose knot in the donor tubing below the "Y" unless alternate methods are used to seal the tubing at the end of collection.

2.4. Temporarily clamp donor tubing between the phlebotomy needle and the "Y".

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. If applicable, secure the needle safety device in place following the device instructions provided on the reverse side.

2.10. Secure donor tubing to donor's arm.

2.11. 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.

2.12. Collect labeled volume of blood 450 mL ±10% or 500 mL ±10%.

2.13. When the desired amount of blood has been collected, seal the tubing or tighten the loose knot (white knot) prepared in Step 2.3. Make a second seal between the first seal or knot and the "Y". Various methods may be used to seal tubing.

2.13.1. **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.

2.14. Anytime before Step # 2.19 below, sever donor tubing between the two seals.

2.15. Assemble the luer adapter and the tube holder. These steps may be performed before or during phlebotomy.

2.15.1. Connect the VENOJECT@Multi-Sample Luer Adapter to the VENOJECT@Tube Holder (or equivalent) (Fig. 1).

2.15.2. Remove covers and connect the multi-sample luer adapter to the female luer at end of Blood Sampling Arm (Fig. 2).

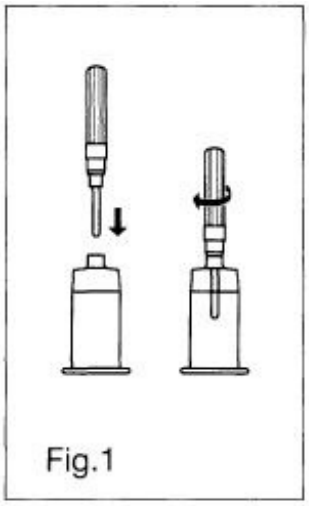


Fig.1

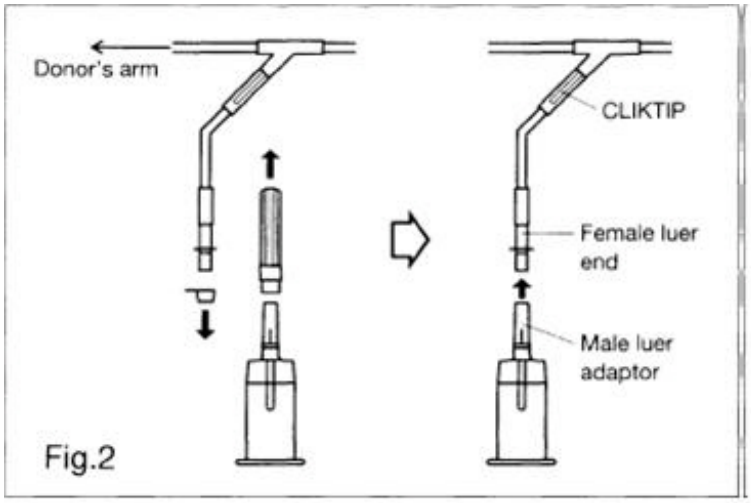


Fig.2

2.16. Collect blood samples as follows:

2.16.1. Break CLIKTIP® (inline closure device) in the Blood Sampling Arm tubing to open blood pathway.

2.16.1.1. **CAUTION:** Do not break CLIKTIP until luer adapter/tube holder assembly is attached to the Blood Sampling Arm.

2.16.2. Insert blood collection tube firmly into the tube holder; when full, remove sample tube from holder. Repeat to collect additional samples.

2.17. Apply a clamp to the donor tubing between the phlebotomy needle and "Y"; release pressure on donor's arm and remove needle. If using a needle safety device, remove the needle into the needle safety device following the device instructions provided on the reverse side.

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

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

2.19. 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.

2.20. The time between Whole Blood collection and component separation may vary depending on both the blood bag system and processing options selected. Follow your institution's standard operating

procedures to prepare components.

2.20.1. If the Whole Blood is to be processed into room temperature components, maintain the blood at ambient temperature.

2.20.2. If the Whole Blood is to be processed into other components (including Plasma Frozen Within 24 Hours After Phlebotomy), Whole Blood must either be placed in storage at a temperature between 1-6°C within 8 hours of blood collection or cooled towards a temperature between 1-10°C (e.g. during transport) and then placed in storage at a temperature between 1-6°C upon arrival at the processing center.

2.21. Platelet Rich Plasma and Platelets should be separated from the Red Blood Cells within 8 hours of blood collection, if prepared.

2.22. Plasma intended for production of Fresh Frozen Plasma should be separated from the Red Blood Cells and placed in a freezer at –18°C or colder within 8 hours of blood collection.

2.23. Plasma intended for production of Plasma Frozen Within 24 Hours After Phlebotomy (PF24) should be placed in a freezer at –18°C or colder within 24 hours of blood collection.

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

2.25. Select the appropriate spin condition and centrifuge Whole Blood unit to separate CPDA-1 Red Blood Cells from plasma or platelet rich plasma, as appropriate.

2.26. Break the CLIKTIP of primary collection bag and transfer plasma into satellite bag, or transfer platelet rich plasma into XT-612® Platelet bag. Clamp transfer tubing of satellite bag.

2.27. Seal tubing of primary collection bag in two places, cut between seals, and if applicable, separate from satellite bag(s).

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

2.29. If prepared, store Platelets between 20-24°C, maintaining a continuous gentle agitation, for up to 5 days in XT-612 bag.

3. DOSAGE FORMS AND STRENGTHS

3.1. 63 mL Citrate Phosphate Dextrose Adenine (CPDA-1) anticoagulant USP for collection of 450 mL Whole Blood. Each 63 mL contains 188 mg Citric Acid (anhydrous) USP, 1.66 g Sodium Citrate (dihydrate) USP, 140 mg Monobasic Sodium Phosphate (monohydrate) USP, 2.01 g Dextrose (monohydrate) USP and 17.3 mg Adenine USP.

3.2. 70 mL Citrate Phosphate Dextrose Adenine (CPDA-1) anticoagulant USP for collection of 500 mL Whole Blood. Each 70 mL contains 209 mg Citric Acid (anhydrous) USP, 1.84 g Sodium Citrate (dihydrate) USP, 155 mg Monobasic Sodium Phosphate (monohydrate) USP, 2.23 g Dextrose (monohydrate) USP and 19.3 mg 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. Do not break CLIKTIP until luer adapter/tube holder assembly is attached to the Blood Sampling Arm.

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

5.12. 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.

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

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

5.15. 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 / PRODUCT SPECIFICATIONS

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 either a 450 mL or 500 mL (nominal capacity 600 mL) primary collection bag containing 63 mL or 70 mL, respectively, Citrate Phosphate Dextrose Adenine (CPDA-1) anticoagulant, The Double blood bag set has one integrally attached empty satellite bag (nominal capacity 400 mL). The Triple blood bag set has one integrally attached empty satellite bag (nominal capacity 400 mL) and one empty XT-612 5 day Platelet bag (nominal capacity 500 mL). The Quadruple blood bag set has two integrally attached empty satellite bags (nominal capacity 400 mL) and one empty XT-612 5 day Platelet bag (nominal capacity 500 mL).

11.2. Blood bag codes ending in A4 are supplied with Integral Blood Sampling Arm for obtaining donor samples for laboratory testing after collection of the Whole Blood unit.

11.3. Blood bag codes ending in A3 also include a DonorCare Needle Guard pre-attached to the donor tubing. DonorCare Needle Guard device instructions are provided on the reverse side.

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

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

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

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

11.8. Donor tubing line maximum 16 segments available.

16. HOW SUPPLIED/STORAGE AND HANDLING

16.1. Single use only.

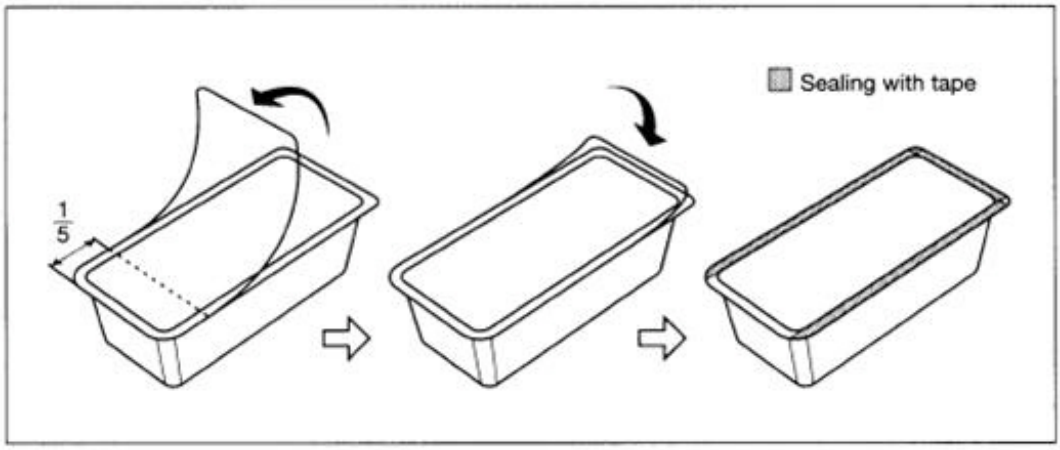
16.2. Sterile and non-pyrogenic fluid path. Sterilized by steam. Opacity of the blood bag system may be observed. This is due to moisture absorption during the sterilization process. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually.

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. For the Single blood bag sets, Codes **BB*SCD456A3** and **BB*SCD506A3** are supplied 36/case, Code **BB*SCD456A4** is supplied 48/case.

16.13. For the Double blood bag sets, Codes **BB*DCD456A3**, **BB*DCD456A4** and **BB*DCD506A3** are supplied 30/case.

16.14. For the Triple blood bag sets, Codes **BB*TCD456A3** and **BB*TCD456A4** are supplied 30/case.

16.15. For the Quadruple blood bag sets, Codes **BB*QCD456A3** and **BB*QCD506A3** are supplied 24/case.

MANUFACTURED BY:

TERUMO CORPORATION

44-1, 2-CHOME, HATAGAYA, SHIBUYA-KU, TOKYO 151-0072, JAPAN

MADE IN JAPAN

®: Registered Trademark

DonorCare is a registered trademark of Noble House Group Pty. Ltd. CORPORATION.

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

PROCEDURE FOR USE OF

DonorCare® Needle Guard

This device is for use by trained individuals.

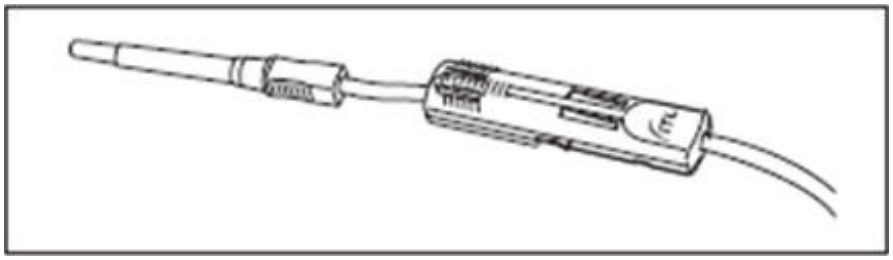
Intended Use

The DonorCare® Needle Guard is incorporated onto the donor tubing to shield the needle immediately after withdrawal from the donor.

Single Use Only.

Preparation

1. Move the DonorCare on the tubing ensuring that it slides easily and the arrow is pointing toward the needle hub.



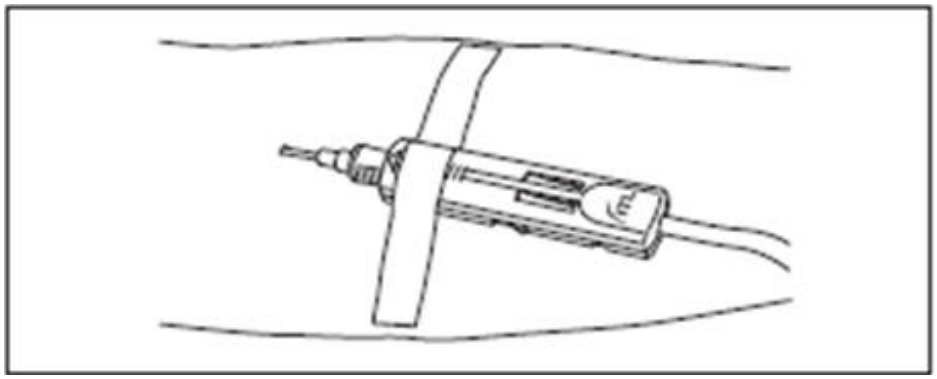
2. Ensure that the three lock points on the DonorCare are locked closed.

Whole Blood Collection

3. Perform the phlebotomy as per your institution's standard operating procedures.

4. Slide the DonorCare over the needle hub so that it covers approximately one half to two thirds of the needle hub.

5. Stabilize the DonorCare to the arm by placing a piece of tape over the front end so that the tape does not extend over the front of the DonorCare.



Withdrawal of Needle

Important

The DonorCare must be held stationary while the needle is withdrawn into it.

Caution

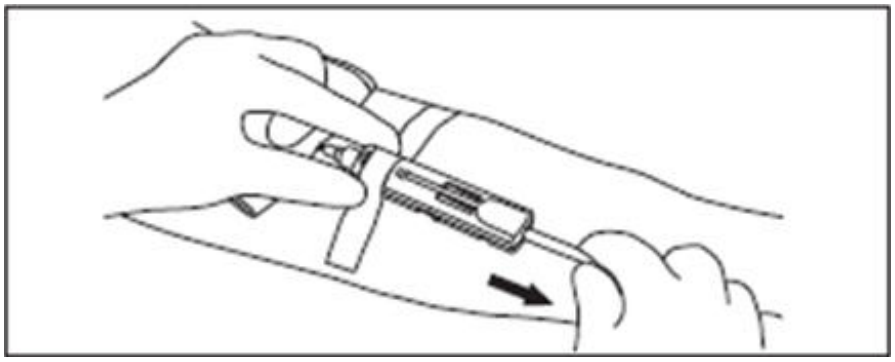
The needle must be fully shielded by DonorCare to prevent accidental injury.

6. Hold gauze over the venipuncture site with finger tips without exerting pressure. Hold the sides of the DonorCare near the front with the index finger and thumb of the same hand.

7. With the other hand, hold the donor tubing close behind the DonorCare.

Note: A hemostat may be placed on the tubing behind the DonorCare when the blood collection is complete.

This will help to prevent blood drops from forming.



8. Pull tubing smoothly and swiftly with one motion until the needle is locked in place inside the DonorCare.

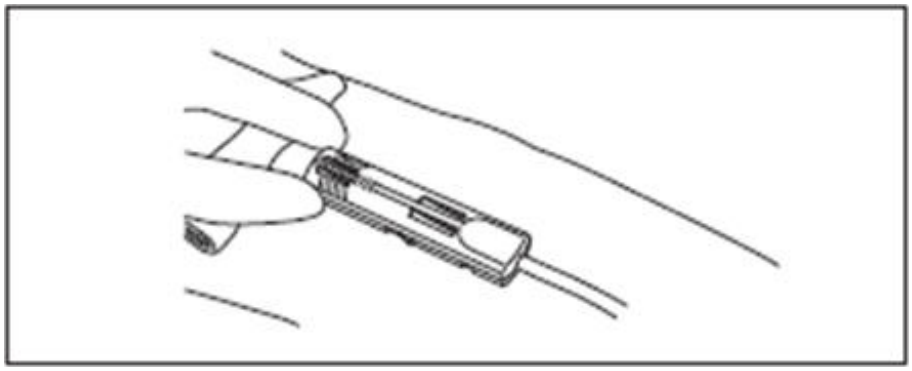
9. Confirm that the needle is locked by:

a. Listening for two 'clicks' as the needle is drawn into DonorCare.

b. If the clicks are not heard as the needle is drawn into the DonorCare, continue to pull firmly on the tubing to assure needle is fully withdrawn into DonorCare.

10. Visually check that the needle is fully shielded by DonorCare before removing from the donor's arm.

11. Remove the tape from the DonorCare and arm.



12. Apply pressure to the gauze covering the venipuncture site.

Warning

Do not place fingers at the opening of DonorCare after removal from the donor's arm.

Difficult Phlebotomy (Examples may include: Slow blood flow, deep or fine vein, steep angle)

It may be necessary to delay placing the DonorCare over the needle hub until the end of the blood collection. In such situations:

Leave the DonorCare on the tubing behind the needle hub. At the end of the blood collection carefully remove the tape from the needle hub and slide the DonorCare over the hub so that it covers approximately one half to two thirds of the needle hub. Withdraw the needle into the DonorCare as stated in steps 6. through 12. above.

Rx ONLY

DonorCare is manufactured by ITL Corporation, Melbourne, Australia.

TERUMO CORPORATION

44-1, 2-CHOME, HATAGAYA, SHIBUYA-KU,

TOKYO 151-0072, JAPAN

Tray/Case Label
TERUFLEX® BLOOD BAG SYSTEM with Blood Sampling Arm™

ANTICOAGULANT CITRATE PHOSPHATE
DEXTROSE ADENINE SOLUTION (CPDA-1) USP
FOR COLLECTION OF 500mL OF BLOOD

Each unit consists of a primary bag containing 70 mL of solution with 209 mg Citric Acid (anhydrous) USP, 1.84 9 Sodium Citrate (dihydrate) USP, 155 mg Monobasic Sodium Phosphate (monohydrate) USP, 2.23 9 Dextrose (monohydrate) USP, 19.3 mg Adenine USP.

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

CODE

LOT NO.

EXPIRY

UNITS

DONOR NEEDLE16G X 1 1/2" (1.60 X 38mm)
RxONLY

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-2-H6-A4-2

TERUMO®

TERUFLEX® BLOOD BAG SYSTEM with Blood Sampling Arm™

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION (CPDA-1) USP FOR COLLECTION OF 500mL OF BLOOD

Each unit consists of a primary bag containing 70 mL of solution with 209 mg Citric Acid (anhydrous) USP, 1.84 g Sodium Citrate (dihydrate) USP, 155 mg Monobasic Sodium Phosphate (monohydrate) USP, 2.23 g Dextrose (monohydrate) USP, 19.3 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-2-H6-A4 ②

TERUFLEX BLOOD BAG SYSTEM ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE (CPDA-1)

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:53877-001-04	48 in 1 CASE		
1		63 mL in 1 BAG; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
2	NDC:53877-001-05	30 in 1 CASE		
2		63 mL in 1 BAG; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
3	NDC:53877-001-06	36 in 1 CASE		
3		70 mL in 1 BAG; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
4	NDC:53877-001-07	30 in 1 CASE		
4		70 mL in 1 BAG; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
5	NDC:53877-001-08	24 in 1 CASE		
5		70 mL in 1 BAG; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
6	NDC:53877-001-09	24 in 1 CASE		
6		63 mL in 1 BAG; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
7	NDC:53877-001-10	36 in 1 CASE		

7		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	BN820528	12/14/2009	

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