ADSOL RED CELL PRESERVATION SOLUTION SYSTEM IN PLASTIC CONTAINER (PL 146 PLASTIC)- anticoagulant citrate phosphate dextrose (cpd) solution and adsol preservation solution
Fenwal, Inc.

4R3428, 4R3429
Fresenius Kabi
Fenwal Blood-Pack Units Rx only
Using Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) with an Integrally Attached Container of Adsol Red Cell Preservation Solution and Fenwal HighFlo Needle

Contains Y-Sampling Site for the collection of unanticoagulated whole blood samples for laboratory testing.

Instructions for Use

Collection Procedure:

Use aseptic technique.

> **Note:** Nominal tubing dimensions of product are 0.118" inner diameter x 0.025" wall thickness.

Note: If the Y-Sampling Site is not used, donor samples may be collected using an alternate method following standard procedures.

> **Precautions:**
> **• Do not use unless the solutions are clear.**
> **• Before beginning procedure, obtain one access device for each Blood-Pack unit with Y-Sampling Site to be processed.**
> 1. Identify Blood-Pack unit using appropriate donor identification system.
> 2. Adjust donor scale to desired collection weight and position primary container on the donor scale as far as possible below donor arm.
> 3. Clamp donor tubing between Fenwal HighFlo[1] needle and primary container. This step may be performed prior to step 1 or 2.
> 4. Following blood center procedures, apply pressure to donor's arm and disinfect site of venipuncture.
> 5. Remove needle cover per instructions below:

- Holding the hub and cover near the tamper-evident seal, twist cover and hub in opposite directions to break seal.
- Remove needle cover, being careful not to drag the cover across the needle point.

6. Following blood center procedures, perform venipuncture, appropriately secure donor needle and/or tubing and release clamp on donor tubing.

7. When good blood flow is established, stabilize the front of the needle guard to arm with tape. (see Figure 1)

8. **Following blood center procedures, mix blood and anticoagulant in primary container at several intervals during collection and immediately after**

collection.

9. Collect the appropriate volume based on Blood-Pack unit used. **Note:** The volume of anticoagulant is sufficient for the blood collection indicated on Blood-Pack unit ± 10%.

10. Release the pressure on the donor's arm as appropriate.

Precaution: Do not proceed with the remaining steps until the entire whole blood unit is collected.

11. To avoid possible contamination of the whole blood unit, before filling whole blood sample tubes, hermetically seal the donor tubing near the Y-Sampling Site on the side leading to the primary container using a metal clip or appropriate alternate method.

Precaution: Complete steps 12 - 20 within approximately 4 minutes after sealing the donor tubing to avoid possible clot formation in the tubing.

12. To collect samples, insert the access device by pushing firmly into the Y-Sampling Site until the membrane seal is penetrated (see Figure 2).

Note: If the access device is assembled such that the outer barrel is screwed onto the Luer, make sure to rotate clockwise upon insertion to avoid barrel detaching from Luer.

13. Open the cap on the access device (if applicable).

14. Directly align the vacuum sample tube with the internal needle in the access device. Insert vacuum sample tube into device until the stopper is punctured.

15. Allow vacuum sample tube to fill with blood then remove from the access device.

16. Repeat steps 14 and 15 until the desired number of vacuum sample tubes have been filled.

Notes:

- **If the access device needs to be replaced, clamp the tubing between the needle and the Y-Sampling Site. Then, grasp base of Sampling Site with one hand and pull the access device out with the other hand. Firmly insert the new access device. Remove clamp and continue sampling.**
- **If the access device is assembled such that the outer barrel is screwed onto the Luer, make sure to rotate clockwise upon removal to avoid barrel detaching from Luer.**
- **The access device can only be replaced one time.**

Precaution: When replacing access device, be careful to avoid contact with any blood droplets on the Luer or sampling site. Discard used access device appropriately.

17. Release remaining pressure on donor's arm.

18. If desired, apply clamp to donor tubing between needle and Y-Sampling Site.

19. **Withdrawal of Needle** (see Figure 3)

Precaution: The needle guard must be held stationary while the needle is withdrawn into it.

a) Place folded sterile gauze over puncture site and hold in place with finger tip without exerting pressure.
b) Hold sides of needle guard near the front, between the index finger and thumb. Pull the hub back smoothly until the needle is completely enclosed and securely locked into the needle guard.
c) Confirm the needle is completely enclosed and securely locked into the needle guard.

20. Strip blood from donor tubing into primary container, mix and allow the tubing to refill; repeat once.

21. Seal at X marks on donor tubing to provide numbered aliquots of anticoagulated blood for typing or crossmatching.

Note: Step 22 may be performed prior to step 20 or 21 if desired.

22. Remove and discard the Y-Sampling Site and the donor needle in the needle guard into an appropriate biohazardous waste container following established procedures.

23. **Component Preparation:**

• If a platelet concentrate is to be prepared, it should be separated from the Red Blood Cells within 8 hours after blood collection.
• Fresh Frozen Plasma should be separated from the Red Blood Cells and placed in the freezer at -18°C or colder within 8 hours after blood collection.
• Adsol Red Cell Preservation Solution should be added to the Red Blood Cells immediately after the removal of plasma. Preparation of AS-1 Red Blood Cells may vary depending on processing option selected:
a) Within 8 hours of blood collection if whole blood is held at ambient temperature.
b) Within 3 days of blood collection if whole blood is refrigerated.

24. At the appropriate time, prepare the Blood-Pack unit for centrifugation by thoroughly mixing the primary container end over end, then load the unit in a centrifuge cup per the instructions on page 3.

25. Following centrifugation, remove containers from the centrifugation cup taking care not to disturb the red blood cell / plasma interface.

26. Place primary container in plasma extractor and express plasma into empty Transfer Pack container by releasing pressure plate and opening closure in tubing of primary container.

27. When desired amount of plasma has been removed, clamp tubing between Y and plasma container.

28. Suspend Adsol Red Cell Preservation Solution Container, open closure in tubing and drain contents into primary container of CPD Red Blood Cells. Clamp tubing.

29. Hermetically seal and separate transfer tubing between the Y-connector and primary container. Be careful to avoid fluid splatter. **Discard Adsol solution container.**

30. Mix Adsol Red Cell Preservation Solution and red cells thoroughly.

31. Store suspended AS-1 Red Blood Cells between 1 and 6°C.

32. Infuse AS-1 Red Blood Cells within 42 days of collection.

Figure 1

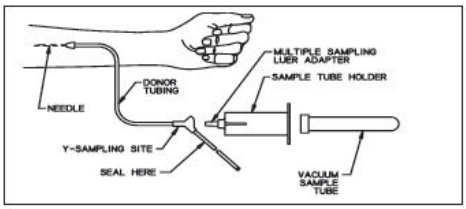


Figure 2

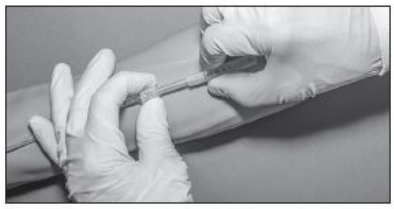
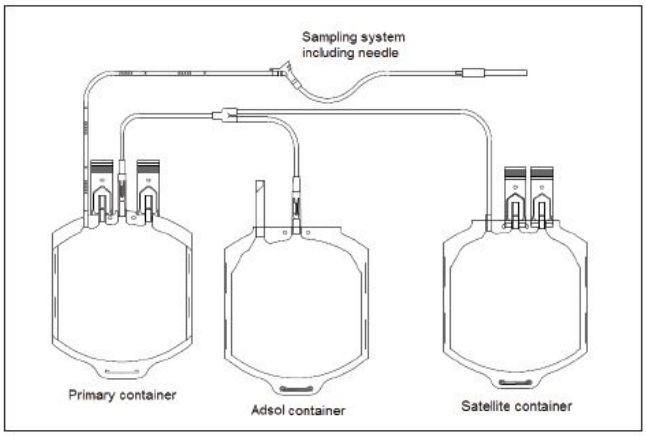


Figure 3



Representative Product Drawing

Store at Controlled Room Temperature. Protect from freezing. Avoid excessive heat.

Definition of “Controlled Room Temperature”:

“A temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15°C and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40°C are permitted as long as they do not exceed 24 hours ... The mean kinetic temperature is a calculated value that may be used as an isothermal storage temperature that simulates the non isothermal effects of storage temperature variations.”

Reference: United States Pharmacopeia, General Notices. United States Pharmacopeial

Convention, Inc. 12601 Twinbrook Parkway, Rockville, MD.

[1] Van der Meer, P.F., & de Korte, D. “Increase of blood donation speed by optimizing the needle-to-tubing connection: an application of donation software.” Vox Sanguinis 2009, 97: 21-25

Symbols with Definitions:

 Caution, consult instructions for use

Sterilized by steam. Sterile fluid path.

 Non-pyrogenic fluid path

 Do not reuse

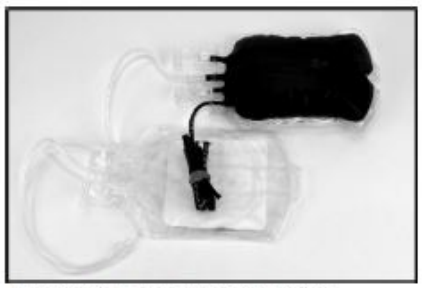
 Do not vent

 This way up

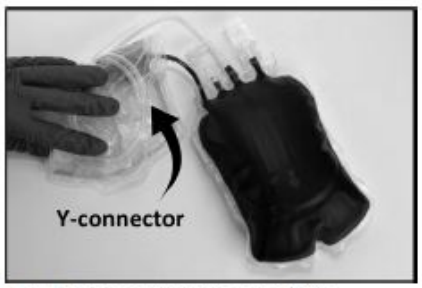
Lot

Code

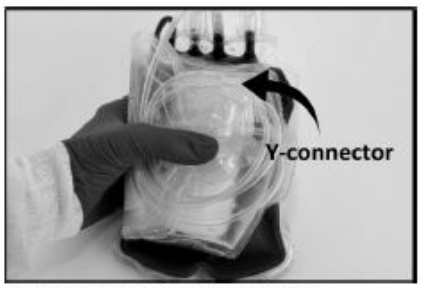
Centrifuge Cup Loading Instructions
BPU without Filter



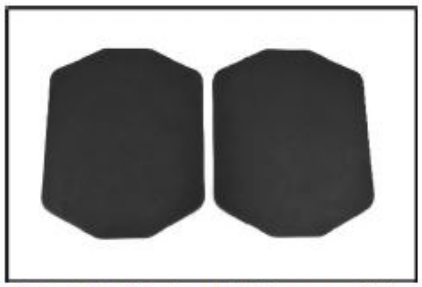
1 Place the Blood-Pack unit on a work surface. Separate the containers keeping the satellite containers together with Adsol container on top and label side down. Place segments on the middle of the satellite containers.



2 Fold satellite containers over segments. Coil tubing on top of folded containers. Ensure Y-connector is at side of folded containers.



3 Place folded satellite containers on primary container as shown. Satellite containers are horizontally placed with tabs/tubing facing out. Y-connector is oriented at the top and the extra tubing is placed to the outside of the bundle.



4 Sorvall® Blood Bag Insert #11365 is recommended for use with oval centrifuge cups or when there is excess space inside the cup. If excess space inside the cup is not filled, the blood bag can over expand and break.

5 If used, inserts are placed on back of bundle. Do not place inserts between satellite containers and primary container or at the front of the primary container.

6 Hold the bundle and insert into the centrifuge cup.

7 Press the satellite containers (and inserts if used) down into the liner before pressing down the primary container.

8 After the satellite containers have been pressed down, press the primary container down into the liner.

9 When finished, the cannula is in the upright position, the Y-connector is at the top away from the primary container, segments are secured inside the satellite containers, and the unit is down inside the cup.

Perform centrifugation according to center procedures.

This guide illustrates one method of cup loading and applies to all non-filter BPU configurations. The specific stacking order and methods may vary depending on the centrifuge equipment and your facility's Standard Operating Procedures. See Directions for Use for complete instructions, precautions, and warnings.

Manufacturer
Fresenius Kabi AG
61346 Bad Homburg / Germany
www.fresenius-kabi.com
1-800-933-6925

47-23-13-535 REV: A

PACKAGE/LABEL DISPLAY PANEL

Code 4R3429 15 Units

Fresenius Kabi

Fenwal Blood-Pack Units Double

Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD); Satellite Container with Adsol Red Cell Preservation Solution

For the Collection and Processing of 500 mL Blood

Y-Sampling Site, 16 ga. Ultra Thin Wall Fenwal HighFlo Needle

Rx only

Each unit consists of a primary container with 70 mL of CPD solution containing 1.84 g Sodium Citrate (dihydrate) USP, 1.78 g Dextrose (monohydrate) USP, 209 mg Citric Acid (anhydrous) USP, 155 mg Monobasic Sodium Phosphate (monohydrate) USP, pH may have been adjusted with sodium hydroxide; one satellite container with 110 mL of Adsol Red Cell Preservation Solution containing 2.42 g Dextrose (monohydrate) USP, 990 mg Sodium Chloride USP, 825 mg Mannitol USP, 30 mg Adenine USP; one empty 400 mL Transfer-Pack container.

Sterile, non-pyrogenic fluid path. See instructions for use.

Single use only.

Store at Controlled Room Temperature (refer to direction insert).

- Open pouch by tearing across at notch.
- Direct handling of product surfaces prior to extended storage in the **foil** pouch, may result in mold growth.
- Unused units in open **foil** pouch may be kept up to 60 days by folding and **securing** open end of **foil** pouch to prevent possible loss of moisture, provided:

  I) Units are not removed from **foil** pouch, or
  II) Unused units removed from **foil** pouch are returned to the **foil** pouch within 12 hours. Units may be removed from the pouch and returned only once.

- Units removed from the **foil** pouch (that are not returned to the pouch within 12 hours) must be used within 4 days (96 hours). Units out of the **foil** pouch for longer than 96 hours must be discarded.

Manufacturer
Fresenius Kabi AG
61346 Bad Homburg / Germany

www.fresenius-kabi.com

Made in US

47-23-13-539 REV: A

Code 4R3429 To Open Tear Across at Notch 15 Units

FRESENIUS KABI

Fenwal Blood-Pack Units Double

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www.fresenius-kabi.com

Made in US

47-28-13-539 REV: A

ADSOL RED CELL PRESERVATION SOLUTION SYSTEM IN PLASTIC CONTAINER (PL 146 PLASTIC)

anticoagulant citrate phosphate dextrose (cpd) solution and adsol preservation solution kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0942-6431

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0942-6431-02	1 in 1 KIT; Type 0: Not a Combination Product		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BAG	70 mL
Part 2	1 BAG	110 mL

Part 1 of 2

CPD

citrate phosphate dextrose 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	1.84 g in 70 mL
Dextrose Monohydrate (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	Dextrose Monohydrate	1.78 g in 70 mL
Anhydrous Citric Acid (UNII: XF417D3PSL) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	209 mg in 70 mL
Sodium Phosphate, Monobasic, Monohydrate (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR)	Sodium Phosphate, Monobasic, Monohydrate	155 mg in 70 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1		70 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN811104	03/01/2007	

Part 2 of 2

ADSOL RED CELL PRESERVATION SOLUTION SYSTEM

adsol red cell preservation solution solution

Product Information

Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextrose Monohydrate (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	Dextrose Monohydrate	2.42 g in 110 mL
Sodium Chloride (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	Sodium Chloride	990 mg in 110 mL
Mannitol (UNII: 3OWL53L36A) (Mannitol - UNII:3OWL53L36A)	Mannitol	825 mg in 110 mL
Adenine (UNII: JAC85A2161) (Adenine - UNII:JAC85A2161)	Adenine	30 mg in 110 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		110 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN811104	03/01/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN811104	03/01/2007	

Labeler - Fenwal, Inc. (794519020)

Establishment

Name	Address	ID/FEI	Business Operations
Fenwal International, Inc.		091164590	MANUFACTURE

Revised: 6/2021 Fenwal, Inc.