

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

Fenwal, Inc.

BLOOD-PACK™ Unit with an Integral SEPACELL™ RS-2000/RZ-2000 Whole Blood Leukocyte Reduction Filter for Collection and Filtration of Whole Blood Using Either CPD/ADSOL™ Red Cell Preservation Solution Or Anticoagulant Citrate Phosphate Dextrose Adenine Solution, USP (CPDA-1)

Rx only

Contains FENWAL EXPRESS™ System. Also contains Y-Sampling Site for the collection of unanticoagulated whole blood samples for laboratory testing and the DONORCARE Needle Guard.

Integral filter unit intended for leukocyte reduction of Whole Blood up to 8 hours after blood collection when Whole Blood is stored at ambient temperature or up to 72 hours after blood collection when Whole Blood is refrigerated. The leukocyte reduced blood products may then be stored for the maximum allowable dating period.

Instructions for Use

Collection Procedure:

Use aseptic technique.

Notes:

Nominal tubing dimensions of product are 0.118” inner diameter x 0.025” wall thickness.

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

Precautions:

Upon removal of BLOOD-PACK unit from the clear plastic overwrap, visually inspect the unit.

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. Donor Scale
 - Adjust donor scale to desired collection weight.
 - Position primary container on the donor scale as far as possible below donor arm.
3. Clamp donor tubing between needle and primary container. This step may be performed prior to step 1 or 2.
4. Apply pressure to donor’s arm and disinfect site of venipuncture.
5. If blood pressure cuff is used, inflate to approximately 60 mmHg.
6. Remove needle cover per instructions below:
 - Holding the hub and cover near the tamper-evident seal, twist cover 1/4 turn to break seal.

- Remove needle cover, being careful not to drag the cover across the needle point.
7. Following blood center procedures, perform venipuncture, appropriately secure donor needle and/or tubing and release clamp on donor tubing.
 8. When good blood flow is established, slide the DONORCARE Needle Guard over the needle hub into the engaged position. Leave the front third of the needle hub exposed for access. Stabilize the front of the needle guard to arm with tape. (see Figure 1)

Note: In difficult collection conditions (e.g., slow blood flow), leave the needle guard disengaged, behind the hub during collection. **Engage the needle guard at the end of blood collection. Appropriately secure needle and/or tubing.**

9. **Following blood center procedures, thoroughly mix blood and anticoagulant in primary container at several intervals during collection and immediately after collection.**
10. 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 \pm 10%.
11. 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.

12. 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 13 - 22 within approximately 4 minutes after sealing the donor tubing to avoid possible clot formation in the tubing.

13. 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.

14. Open the cap on the access device (if applicable).
15. 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.
16. Allow vacuum sample tube to fill with blood then remove from the access device.
17. Repeat steps 15 and 16 until the desired number of vacuum sample tubes have been filled.

Notes:

If the access device needs to be replaced, use a hemostat to 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 as before. Remove hemostat 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 the access device, be careful to avoid contact with any blood droplets on the Luer or Sampling Site. Discard used access device appropriately.

18. Release remaining pressure on donor's arm.
19. If desired, apply hemostat to donor tubing between needle and Y-Sampling Site.
20. **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 tubing smoothly until the needle is locked into the needle guard.
 - c) Confirm the needle lock by:
 - Listen for the 2nd "click" as the needle is drawn into the needle guard.
 - Ensure the tubing cannot be pulled through the needle guard.
21. Remove and discard the Y-Sampling Site and needle guard into an appropriate biohazardous waste container following established procedures. If donor tubing is also to be discarded, hermetically seal donor tubing directly above the primary container and remove.

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

22. If the donor tubing is not hermetically sealed directly above the primary container, then strip the blood from the remaining donor tubing into the primary container. Mix and allow tubing to refill; repeat once.

Filtration Procedure:

Precaution: Whole blood collected from certain donors may have extended filtration times and the potential for ineffective filtration and leukoreduction.

Note: The time of Whole Blood filtration may vary depending on processing option selected.

- a) Within 8 hours of collection if Whole Blood is held at ambient temperature.
 - b) Within 72 hours of collection if Whole Blood is refrigerated following collection.
23. **Mix unfiltered Whole Blood thoroughly.** Invert the primary container and hang the filter set such that the filter remains vertical. To achieve maximum flow rate, allow set to hang to full length.

Note: The filtered Whole Blood container must remain below the level of the filter during filtration. For proper air expression to occur, ensure the filtered Whole Blood container is vertical.

24. Inspect all tubing to insure it hangs freely without kinks. Install and close clamp on bypass line.
25. Break the in-line cannula above the filter to start filtration. To completely break the in-line cannula, grasp with both hands. Snap it at a 90° angle in one direction, and then bend it at a 90° angle in the opposite direction. Allow filtration to continue until flow stops.

Note: Manual or mechanical pressure should not be used to increase the flow rate through the filter.

Note: Tubing below the filter should not be stripped at any time during the filtration process.

Note: If the filtration of Whole Blood is initiated at ambient temperature and not completed within 8 hours after blood collection, then filtration should be completed between 1 and 6°C.

Note: If recovery of residual blood in the primary container is desired, install and close a clamp on the segment line prior to removing the clamp on the bypass line. The segment line clamp can then be removed after step 26.

26. Open the clamp on the bypass line and allow air to transfer from the filtered Whole Blood container to the primary container.

Note: If desired, gently squeeze the filtered Whole Blood container to transfer remaining air through the bypass line.

27. Allow filtration to continue until the inlet side of the filter is filled with air.
28. Hermetically seal and separate the bypass line above the filtered Whole Blood container. Also hermetically seal and separate the segment line tubing directly above the top donor segment number. Use care to avoid fluid splatter. Discard filter and primary container appropriately.

Note: If a QC sample is desired, thoroughly mix the filtered Whole Blood and strip the donor segment tubing or bypass line tubing as desired. Use the tubing farthest away from the filtered Whole Blood container as the QC sample.

29. Make donor segments. Leave segments attached to the filtered Whole Blood container.

Component Preparation Procedure:

Note: Platelet concentrates are not intended to be made with this product.

30. Centrifuge filtered Whole Blood and secondary containers to prepare CPD/CPDA-1 Red Blood Cells using the appropriate spin condition.

Note: It is recommended that the filtered Whole Blood container and secondary container(s) be loaded into the centrifuge cups with a snug fit and that contact with rigid components is avoided.

31. Place filtered Whole Blood container in plasma extractor, and express plasma into empty TRANSFER-PACK™ container by releasing pressure plate and opening closure in tubing of filtered Whole Blood container.
32. When the desired amount of plasma has been removed, clamp the tubing between Y and plasma container. Hermetically seal and separate transfer tubing being careful to avoid fluid splatter.

Note: If applicable, 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:

- Within 8 hours of blood collection if whole blood is held at ambient temperature.
 - Within 3 days of blood collection if whole blood is refrigerated.
33. If applicable, suspend ADSOL Red Cell Preservation Solution container; open closure in tubing and drain contents onto CPD Red Blood Cells. Clamp tubing.
 34. Hermetically seal and separate transfer tubing near the container of filtered Red Blood Cells. Be careful to avoid fluid splatter. **For double BLOOD-PACK unit ADSOL products, discard**

ADSOL Solution Container. For all other ADSOL products, the empty solution container may now be used as a TRANSFER-PACK container for further component preparation.

35. For further processing of plasma product with multiple BLOOD-PACK units, use standard component processing and storage techniques.

Note: 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.

36. If set contains ADSOL Red Cell Preservation Solution, mix the ADSOL Red Cell Preservation Solution and Red Blood Cells thoroughly, producing AS-1 Red Blood Cells, Leukocytes Reduced.
37. Store suspended AS-1 Red Blood Cells, Leukocytes Reduced, or suspended CPDA-1 Whole Blood/Red Blood Cells, Leukocytes Reduced, (as applicable) between 1 and 6°C.
38. Infuse AS-1 Red Blood Cells, Leukocytes Reduced, within 42 days of collection, and CPDA-1 Whole Blood/Red Blood Cells, Leukocytes Reduced, within 35 days of collection.

Warning: Failure to achieve closed system processing conditions negates the extended storage claim and the red blood cell product must be transfused within 24 hours.

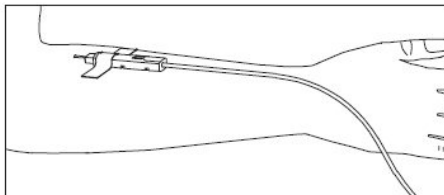


Figure 1

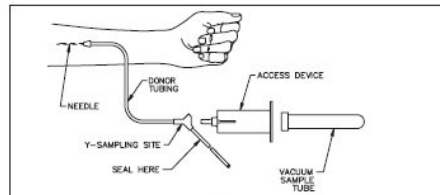


Figure 2

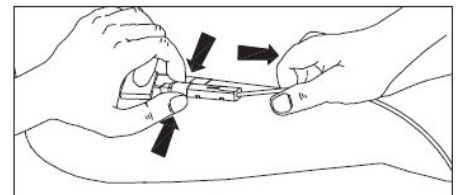
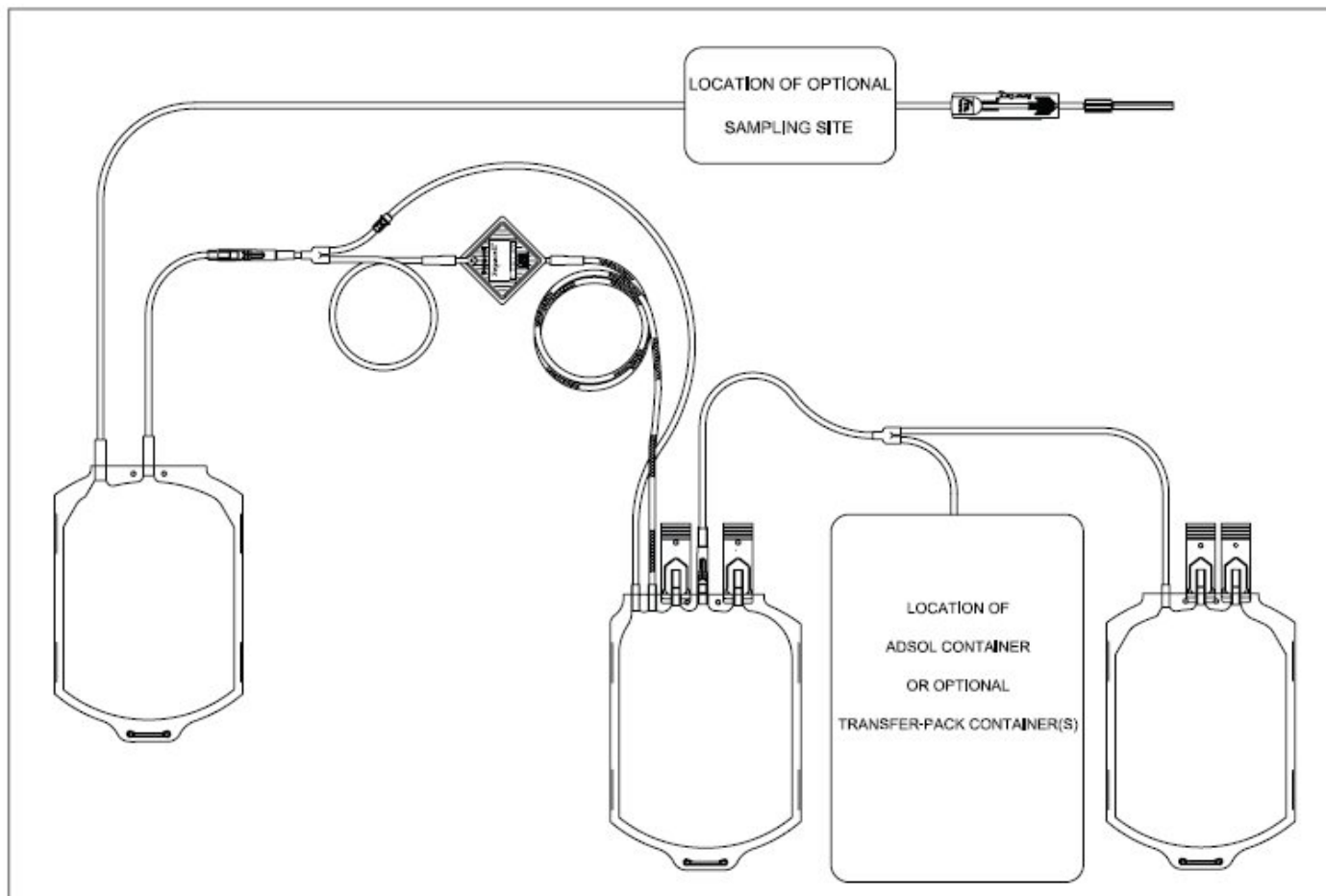



Figure 3



Representative Product Drawing

Store at Controlled Room Temperature.
 USP Definition of “Controlled Room Temperature”
 United States Pharmacopeia, General Notices.
 United States Pharmacopeial Convention, Inc.
 12601 Twinbrook Parkway, Rockville, MD

 – Manufacturer

 **Fenwal, Inc.**
 Lake Zurich, IL 60047 USA

1-800-933-6925

Made in USA

07-19-07-482 REV: A
 09/2012

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SEPACELL is a registered trademark of Asahi Kasei Medical Co., Ltd.

DONORCARE is a trademark of ITL Corporation.

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PACKAGE/LABEL DISPLAY PANEL

Code 4R3307E

10 Units

Fenwal™

Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) BLOOD-PACK™ Unit; TRANSFER-PACK™ Container with ADSOL™ Red Cell Preservation Solution; Integral SEPACELL™ Leukocyte Reduction Filter for Whole Blood

Double For the Collection and Processing of 500 mL Blood

FENWAL EXPRESS™ System, Y-Sampling Site, DONORCARE™ Needle Guard, 16 ga. Ultra Thin Wall Needle

Rx only

Each unit consists of a PL 146 Plastic 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 PL 146 Plastic 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 PL 146 Plastic TRANSFER-PACK™ container; one integral SEPACELL™ Leukocyte Reduction Whole Blood Filter and one empty 450 mL PL 146 Plastic TRANSFER-PACK container for the storage of AS-1 red blood cells, leukocytes reduced.

**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.

Sterile, non-pyrogenic fluid path.

See instructions for use.

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SEPACELL is a trademark of Asahi Kasei Medical Co., Ltd.

DONORCARE is a trademark of ITL Corporation.



Fenwal, Inc.

Lake Zurich, IL 60047 USA

Made in USA

07-28-05-583 REV: A

Code 4R3307E

10 Units



Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) BLOOD-PACK™ Unit; TRANSFER-PACK™ Container with ADSOL™ Red Cell Preservation Solution; Integral SEPACELL™ Leukocyte Reduction Filter for Whole Blood

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07-28-05-583 REV: A

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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:0942-6482

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0942-6482-02	1 in 1 KIT		

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
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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	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)	

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	BN8 11104	06/11/2007	

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: 451W47IQ8 X) (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

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	BN8 11104	06/11/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN8 11104	06/11/2007	

Labeler - Fenwal, Inc. (794519020)

Registrant - Fenwal, Inc. (794519020)