Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) Blood-Pack™ Unit for the Collection of 450 mL of Whole Blood for Autologous Transfusion

Instructions for use
Use aseptic technique:

Rx only

Notes:

* For use with a 4C2498 Y-Type Connector set with Luer connector. If an alternate set is used, follow manufacturers instructions for use.
* Nominal tubing dimensions of product are 0.118" inner diameter x 0.025" wall thickness.
* Upon removal of Blood-Pack unit from the foil pouch, visually inspect the unit.

Caution: Do not use unless solutions are clear.

1. Identify Blood-Pack unit using appropriate donor identification system for autologous transfusion.
3. Remove protector from the inlet tubing of the Blood-Pack unit(s).
4. Remove protector from the coupler on one lead of the set by slightly pushing on one side of the cap and then pulling the cap in a straight direction. Insert coupler into the inlet tubing of the Blood-Pack unit with a twisting motion until firmly seated.
5. Repeat step 4 with second Blood-Pack unit and the remaining lead on the Y-Type Connector set if a second unit is to be collected.
6. Prime the set with anticoagulant from one Blood-Pack unit by slowly opening clamp on one lead of the set to permit the solution to completely fill the set. Close clamp.
7. Place the Blood-Pack unit(s) in an inverted position below the level of the blood withdrawal site.
8. Attach lead with Luer connector to the arterial line, central venous pressure line, or peripheral venous line access.

Provision should be made to replace the volume of blood collected either prior to or simultaneously with the collection in a manner prescribed by the attending physician.

9. To begin collection, open the clamp on the patient access line and the lead that was used to prime the Y-Type Connector set. Collect 450 mL ± 10% of blood in the first Blood-Pack unit. Mix blood and anticoagulant solution while filling. Close clamp on the lead of the Y-Type Connector set.

Note:

* Use a scale or other appropriate means to ensure adequate collection of proper volume.

10. If a second unit is to be collected, open the clamp on the patient access line and the lead that was used to prime the Y-Type Connector set. Collect 450 mL ± 10% of blood in the second Blood-Pack unit. Mix blood and anticoagulant solution while filling. Close clamp on the lead of the Y-Type Connector set.
Precaution:

• **Collection of the second unit should be initiated within approximately 4 minutes of collection of the first unit to avoid possible clot formation in the tubing.**

11. Close or clamp the access line to prevent blood loss or air getting into the system or patient. Disconnect the Luer connector from the access line.

Precaution:

• **Steps 12-15 should be performed within approximately 4 minutes after collection to avoid possible clot formation in the tubing.**

12. If donor samples are desired, collect donor samples following established procedures.
13. Seal inlet tubing of the Blood-Pack unit(s).
14. If the inlet tubing is not sealed directly above the collection container, then strip the blood from the remaining inlet tubing into the collection container. Mix and allow tubing to refill; repeat once. Seal tubing at X marks on the inlet tubing and leave segments attached to the collection container.
15. Mix blood and anticoagulant solution, label and store in appropriate manner.

Caution: This Blood-Pack unit is for autologous transfusion only. Blood collected should be stored at conditions appropriate for an autologous collection. Store at 1-6°C and reinfuse within 24 hours of collection.

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Fenwal, Inc.
Lake Zurich, IL 60047 USA
Made in USA
07-19-54-238 Iss. 11/2007

PACKAGE/LABEL DISPLAY PANEL
Code 4R0499
2 Units

Fenwal™
Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) BLOOD-PACK™ Unit
Single For Collection of 450 mL of Autologous Blood

Rx only
Each unit consists of a PL 146 Plastic primary container with 63 mL of CPD solution containing 1.66 g Sodium Citrate (dihydrate) USP, 1.61 g Dextrose (monohydrate) USP, 188 mg Citric Acid (anhydrous) USP and 140 mg Monobasic Sodium Phosphate (monohydrate) USP. pH may have been adjusted with sodium hydroxide.

Sterile, non-pyrogenic fluid path.
See direction insert.

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

• 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.

- Direct handling of product surfaces prior to extended storage in the foil pouch, may result in mold growth.
- Units removed from the foil pouch must be used within 4 days (96 hours). Units out of the foil pouch for longer than 4 days must be discarded.
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- 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.
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**Product Information**

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<tr>
<th>Product Type</th>
<th>HUMAN PRESCRIPTION DRUG</th>
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<tr>
<td>Route of Administration</td>
<td>INTRAVENOUS</td>
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<td>Item Code (Source)</td>
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**Active Ingredient/Active Moiety**

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<th>Ingredient Name</th>
<th>Basis of Strength</th>
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<td>CPD</td>
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<tr>
<td><strong>TRISODIUM CITRATE DIHYDRATE</strong> (UNII: B22547B95K) (Anhydrous Citric Acid - UNII:XF417D3PSL)</td>
<td>Anhydrous Citric Acid</td>
<td>1.66 g in 63 mL</td>
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<tr>
<td><strong>DEXTROSE MONOHYDRATE</strong> (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R00K)</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>1.61 g in 63 mL</td>
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<td><strong>ANHYDROUS CITRIC ACID</strong> (UNII: XF417D3PSL) (Anhydrous Citric Acid - UNII:XF417D3PSL)</td>
<td>ANHYDROUS CITRIC ACID</td>
<td>188 mg in 63 mL</td>
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<td><strong>SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE</strong> (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR)</td>
<td>SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE</td>
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**Inactive Ingredients**

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<th>Ingredient Name</th>
<th>Strength</th>
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<td>SODIUM HYDROXIDE (UNII: 55X04QC32I)</td>
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**Packaging**

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**Marketing Information**

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<td>NDA</td>
<td>BN170401</td>
<td>03/01/2007</td>
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**Labeler** - Fenwal, Inc. (794519020)

Revised: 11/2019  Fenwal, Inc.