

NUTRICEL ADDITIVE SYSTEM - CP2D- cp2d/as-3 anticoagulant and additive system solution
NUTRICEL ADDITIVE SYSTEM - AS-3- cp2d/as-3 anticoagulant and additive system solution
Medsep Corporation

CP2D/AS-3 Blood Collection and Sampling System

DESCRIPTION

CP2D/AS-3 Blood Collection and Sampling System with Nutricel Additive System

Instruction for Use for Systems Containing a Y Sampling Site (YSS) or Sample Diversion Pouch (with or without a pre-attached SampLok Vacuum Tube Holder).

Refer to unit foil package label for specific product description being used.

Sterile, nonpyrogenic fluid path. Sterilized by steam.

Rx only.

This product is free of natural rubber latex.

INDICATIONS AND USAGE

For collection of blood and preparation of red blood cells, plasma and platelets.

WARNINGS

Failure to achieve and maintain a closed system during processing would result in a product that must be transfused within 24 hours.

GENERAL PRECAUTIONS

Use aseptic technique. Use only if solutions are clear. If preparing a platelet concentrate, the platelet-rich plasma should be separated from the red blood cells within 8 hours after blood collection. If preparing fresh frozen plasma, separate from the red blood cells and place in the freezer at -18 °C or colder within 8 hours after collection.

* During processing, always observe the following precautions:

1. Sealing should be done in a manner that avoids fluid splatter.
2. Always dispose of blood-contaminated products in a manner consistent with established **BIOHAZARD** safety procedures.

STORAGE

Store CP2D/AS-3 preserved red blood cells at 1—6 °C for up to 42 days and use as indicated.

If AS-3 is not used, whole blood or red blood cells in CP2D alone may be stored at 1—6 °C for up to 21 days.

BLOOD COLLECTION INSTRUCTIONS FOR SYSTEMS CONTAINING A Y SAMPLING SITE (YSS) ONLY

1. Load blood agitation device or suspend blood bag on donor scale and adjust donor scale to desired collection gross weight as per manufacturer's instructions.

2. Clamp donor tubing between DonorCare Needle Guard (DCNG) and Y Sampling Site.
3. Secure donor tubing above the Y connector and disinfect site of phlebotomy.
4. If using blood pressure cuff, inflate to not more than 60 mm Hg.
5. Remove donor needle cover and accomplish phlebotomy.
6. Release clamp and ensure there is blood flow. Reduce pressure as required.
7. Slide the DCNG midway over the needle hub and securely tape DCNG to the donor's arm as close to the top of the DCNG as possible. **Note:** If blood flow is slow, slide DCNG away from the needle hub, adjust and re-engage DCNG. If repeated needle adjustment is necessary, slide DCNG away from the needle hub and re-engage at the end of blood collection.
8. Collect appropriate volume of blood into collection bag, as indicated on packaging. **Note:** Mix blood and anticoagulant frequently during collection, for example, once every 45 seconds, and immediately after collection. If blood agitation device is used, follow manufacturer's operating instructions.
9. After required amount of blood has been collected, seal donor tubing close to Y Sampling Site.*
10. For blood sampling, remove the Y Sampling Site needle cover. Ensure the protective sheath is in place over the sampling needle.
11. Fasten the vacuum tube holder on to the base of the sampling needle.
12. Collect blood samples into vacuum tubes.
13. Ensure the vacuum tubes are centered within the vacuum tube holder during sample collection.
14. Maintain forward pressure on the vacuum tubes during sample collection. **Note:** After the last tube is collected, it is recommended that the vacuum tube holder be left in place.
15. After blood samples are collected, clamp donor tubing between the Y Sampling Site and DCNG, and as close to the DCNG as possible.
16. Release any remaining pressure from the donor's arm.
17. DCNG must be held stationary while the needle is withdrawn into it. While holding sides of DCNG near the front, grasp the tubing below the clamp and pull the needle into the DCNG until it locks into place, and the needle hub engages the bottom of the DCNG.
18. Insert the DCNG into the vacuum tube holder. **Note:** It is recommended that the DCNG be inserted securely into the vacuum tube holder, prior to discarding.
19. Seal donor tubing adjacent to DCNG.* Detach and discard needle, DCNG, Y Sampling Site and tubing.*
20. Strip tubing between seal and collection bag.
21. Continue to "Processing Instructions", Step 1.

BLOOD COLLECTION INSTRUCTION FOR SYSTEMS CONTAINING A SAMPLE DIVERSION POUCH WITH OR WITHOUT A PRE-ATTACHED SAMPLOK VACUUM TUBE HOLDER

When using systems with a pre-attached SampLok vacuum tube holder, follow instructions as noted below, but refer to "When Using Systems with a Pre-attached SampLok Vacuum Tube Holder" when indicated to do so.

1. Load blood agitation device or suspend blood bag on donor scale and adjust donor scale to desired collection gross weight as per manufacturer's instructions.
2. Clamp donor tubing between DonorCare Needle Guard (DCNG) and Sampling Site.

3. Secure donor tubing above the Y connector and disinfect site of phlebotomy.
4. If using blood pressure cuff, inflate to not more than 60 mm Hg.
5. Remove donor needle cover and accomplish phlebotomy.
6. Release clamp and ensure there is blood flow.
7. Slide the DCNG midway over the needle hub and securely tape DCNG to the donor's arm as close to the top of the DCNG as possible. **Note:** If blood flow is slow, slide DCNG away from the needle hub, adjust and re-engage DCNG. If repeated needle adjustment is necessary, slide DCNG away from the needle hub and re-engage at the end of blood collection.
8. The donor blood will be automatically diverted to the sample diversion pouch. Once the sample diversion pouch is filled, close clamp immediately on tubing between the sample diversion pouch and Y connector. **Warning:** To avoid risk of air embolism to donor, do not squeeze sample diversion pouch while tubing is open.
9. Open snap-open closure between the Y connector and the collection bag to initiate blood collection. Reduce pressure as needed.
10. Permanently seal tubing between the sample diversion pouch and the Y connector to maintain sterility of the system prior to collecting blood samples.* **Note:** When using systems with a pre-attached SampLok vacuum tube holder, go to “When Using Systems with a Pre-attached SampLok Vacuum Tube Holder”.
11. For blood sampling, remove the Sampling Site needle cover. Ensure the protective sheath is in place over the sampling needle.
12. Fasten the vacuum tube holder on to the base of the sampling needle.
13. Position the sample diversion pouch downwards so that the air rises to the top of the pouch and away from the vacuum tube holder. **Note:** Drawing air into the vacuum tube may cause hemolysis.
14. Collect blood samples from the sample diversion pouch into vacuum tubes within approximately four minutes to avoid possible clot formation.
15. Ensure the vacuum tubes are centered within the vacuum tube holder during sample collection.
16. Maintain forward pressure on the vacuum tubes during sample collection. **Note:** After the last tube is collected, it is recommended that the vacuum tube holder be left in place.
17. Collect appropriate volume of blood into collection bag as indicated on packaging. **Note:** Mix blood and anticoagulant frequently during collection, for example, once every 45 seconds, and immediately after collection. If blood agitation device is used, follow manufacturer's operating instructions.
18. After required amount of blood has been collected, seal donor tubing close to snap-open closure.*
19. Clamp donor tubing between the Y connector and DCNG, as close as possible to the DCNG.
20. Release any remaining pressure from donor's arm.
21. DCNG must be held stationary while the needle is withdrawn into it. While holding sides of DCNG near the front, grasp the tubing below the clamp and pull the needle into the DCNG until it locks into place, and the needle hub engages the bottom of the DCNG.
22. Insert the DCNG into the vacuum tube holder, if desired. **Note:** It is recommended that the DCNG be inserted securely into the vacuum tube holder, prior to discarding.
23. Seal donor tubing adjacent to DCNG.* Detach and discard needle, DCNG, sample diversion pouch and tubing.*
24. Strip tubing between seal and collection bag.
25. Continue to “Processing Instructions”, Step 1.

WHEN USING SYSTEMS WITH A PRE-ATTACHED SAMPLOK VACUUM TUBE HOLDER

1. To collect blood samples, open lid from SampLok vacuum tube holder.
2. Open snap-open closure between sample diversion pouch and SampLok vacuum tube holder.
3. Position the sample diversion pouch downwards so that the air rises to the top of the pouch and away from the SampLok vacuum tube holder. **Note:** Drawing air into the vacuum tube may cause hemolysis.
4. Collect blood samples from the sample diversion pouch into vacuum tubes within approximately four minutes to avoid possible clot formation.
5. Ensure the vacuum tubes are centered within the SampLok vacuum tube holder during sample collection.
6. Maintain forward pressure on the vacuum tubes during sample collection.
7. The lid may be closed on the SampLok vacuum tube holder after sample collection.
8. Return to “Blood Collection Instruction for Systems Containing a Sample Diversion Pouch with or without a Pre-attached SampLok Vacuum Tube Holder”, Step 17. **Note:** When collection of unit is complete, and the donor needle is engaged in the DCNG, open the lid of the SampLok vacuum tube holder and insert the DCNG into the holder. Twist until it locks into place. An audible click will confirm that it is locked.

PROCESSING INSTRUCTIONS

1. Process whole blood within 72 hours of collection.
2. Mix whole blood/anticoagulant thoroughly.
3. Load whole blood and satellite bags into centrifuge cup, ensuring that the tubing stays in the top half of the cup.
4. Centrifuge at appropriate conditions to produce desired components.
5. Carefully remove the unit from the centrifuge and place the red cell storage bag in the plasma expressor.
6. Clamp tubing to extra satellite bags, if present.
7. Gently apply expressor pressure.
8. Open snap-open closure to satellite bag and express plasma.
9. After plasma is expressed, clamp tubing between red cell storage bag and Y connector, and release expressor pressure.
10. Clamp tubing between the Y connector and plasma bag.
11. Hang AS-3 bag above red cell storage bag and remove clamp from tubing to the red cell storage bag.
12. Open snap-open closure on the bag containing the AS-3 additive solution and transfer to the bag containing the red cells. **Note:** AS-3 solution should be added to the packed red blood cells immediately after removal of plasma. Transfer AS-3 solution under one of the following processing conditions:
 - a. within 8 hours of collection if whole blood is held at room temperature.
 - b. within 72 hours of collection if whole blood is refrigerated.
13. Seal tubing and detach the bag containing packed red cells, and set aside plasma for further processing.*

14. Gently mix packed red cells and AS-3 solution.

15. Store CP2D/AS-3 preserved red blood cells at 1—6 °C for up to 42 days and use as indicated.

Note: If AS-3 is not used, whole blood or red blood cells in CP2D alone may be stored at 1—6 °C for up to 21 days.

HOW SUPPLIED

Each shipping case contains 8 foil envelopes. Within each foil envelope resides 3 clear pouches containing an individual collection system. Each collection system consists of CP2D/AS-3 500 ml, Double Blood Bag Collection System with Nutricel Additive Solution and Sample Diversion Pouch.

Collection Date	Unit Number	EXPIRES
AS-3 RED BLOOD CELLS ADENINE - SALINE ADDED 16.5 mEq sodium added. 04230		ANTICOAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION
From 500 ml CP2D Whole Blood. Store at 1—6 °C.		70 ml Anticoagulant Citrate Phosphate Double Dextrose Solution for collection of 500 ml of blood. Each 70 ml of CP2D solution contains 3.57 g dextrose (monohydrate), USP; 1.84 g sodium citrate (dihydrate), USP; 0.229 g citric acid (monohydrate), USP; and 0.155 g monobasic sodium phosphate (monohydrate), USP. Use only if solution is clear.
See circular of information for indications, contraindications, cautions and methods of infusion.		670120921
VOLUNTEER DONOR This product may transmit infectious agents. Rx only. PROPERLY IDENTIFY INTENDED RECIPIENT.		CP2D ATX Collection/Processing I.D. Label Here
120-92 [LOT]		Medtronic Corporation A Subsidiary of Pall Corporation Covina, CA 91722, USA
1PA0012092		

Collection Bag Label

CP2D 500 ANTICOAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION

AS-3 RED BLOOD CELLS, ADENINE - SALINE ADDED, 16.5 mEq sodium added.

From 500 ml CP2D Whole Blood. Store at 1—6 °C.

70 ml Anticoagulant Citrate Phosphate Double Dextrose Solution for collection of 500 ml of blood. Each 70 ml of CP2D solution contains 3.57 g dextrose (monohydrate), USP; 1.84 g sodium citrate (dihydrate), USP; 0.229 g citric acid (monohydrate), USP; and 0.155 g monobasic sodium phosphate (monohydrate), USP. Use only if solution is clear.

See circular of information for indications, contraindications, cautions and methods of infusion. **VOLUNTEER DONOR.** This product may transmit infectious agents. **Rx only.** **PROPERLY IDENTIFY INTENDED RECIPIENT.**

120-92

Collection Date	Unit Number	EXPIRES
 <p>Place Product Label here after bag is filled.</p> <p>See circular of information for indications, contraindications, cautions and methods of infusion.</p> <p>VOLUNTEER DONOR</p> <p>This product may transmit infectious agents. Rx only.</p> <p>PROPERLY IDENTIFY INTENDED RECIPIENT.</p>	 02 After grouping label here after all required testing has been completed.	075120921
	 <p>CP2D</p> <p>After Collection Processing i.D. Label Here</p>	Medsep Corporation A Subsidiary of Pall Corporation Covina, CA 91722, USA
120-92 <input type="checkbox"/> LOT	 3PA0012092	

Plasma Bag Label

CP2D 500

See circular of information for indications, contraindications, cautions and methods of infusion. **VOLUNTEER DONOR.** This product may transmit infectious agents. Rx only. **PROPERLY IDENTIFY INTENDED RECIPIENT.**

120-92

<p>AS-3 ADDITIVE SOLUTION</p> <p>110 mL of preservative AS-3 contains: 1.21 g Dextrose (monohydrate), USP; 0.647 g Sodium Citrate (dihydrate), USP; 0.451 g Sodium Chloride, USP; 0.304 g Monobasic Sodium Phosphate (monohydrate), USP; 0.046 g Citric Acid (monohydrate), USP; 0.033 g Adenine. Contains 16.5 mEq of Sodium. Use only if solution is clear.</p> <p>Do Not Store Any Blood Components In This Bag. Discard Bag After Using. See Direction Sheet.</p> <p>14-3127-120</p>

Additive Bag Label

AS-3 ADDITIVE SOLUTION

110 mL of preservative AS-3 contains: 1.21 g Dextrose (monohydrate), USP; 0.647 g Sodium Citrate (dihydrate), USP; 0.451 g Sodium Chloride, USP; 0.304 g Monobasic Sodium Phosphate (monohydrate), USP; 0.046 g Citric Acid (monohydrate), USP; 0.033 g Adenine. Contains 16.5 mEq of Sodium. Use only if solution is clear.

Do Not Store Any Blood Components In This Bag. Discard Bag After Using. See Direction Sheet.

14-3127-120



MANUFACTURER

Medsep Corporation, A Subsidiary of Pall Corp., Covina, CA 91722, USA

Visit us at www.pall.com/medical

For Pall customer service, call: 1.800.645.6578

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NUTRICEL ADDITIVE SYSTEM - CP2D

cp2d/as-3 anticoagulant and additive system solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62646-120
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (DEXTROSE - UNII:IY9XDZ35W2)	DEXTROSE MONOHYDRATE	3.57 g in 70 mL
SODIUM CITRATE (UNII: 1Q73Q2JULR) (CITRIC ACID - UNII:2968PHW8QP)	SODIUM CITRATE	1.84 g in 70 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (CITRIC ACID - UNII:2968PHW8QP)	CITRIC ACID MONOHYDRATE	0.229 g in 70 mL
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) (PHOSPHORUS - UNII:27YLU75U4W)	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	0.155 g in 70 mL

Product Characteristics

Color	yellow (yellowish solution)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62646-120-BX	8 in 1 BOX		
1	NDC:62646-120-PO	3 in 1 POUCH		
1	NDC:62646-120-92	70 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA820915	02/01/2012	

NUTRICEL ADDITIVE SYSTEM - AS-3

cp2d/as-3 anticoagulant and additive system solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62646-AS3
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (DEXTROSE - UNII:IY9XDZ35W2)	DEXTROSE MONOHYDRATE	1.21 g in 110 mL
SODIUM CITRATE (UNII: 1Q73Q2JULR) (CITRIC ACID - UNII:2968PHW8QP)	SODIUM CITRATE	0.647 g in 110 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIC ACID - UNII:Z0V9L75HBK)	SODIUM CHLORIDE	0.451 g in 110 mL
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) (PHOSPHORIC ACID - UNII:E4GA8884NN)	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	0.304 g in 110 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (CITRIC ACID - UNII:2968PHW8QP)	CITRIC ACID MONOHYDRATE	0.046 g in 110 mL
ADENINE (UNII: JAC85A2161) (ADENINE - UNII:JAC85A2161)	ADENINE	0.033 g in 110 mL

Product Characteristics

Color	yellow (yellowish solution)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62646-AS3-BX	8 in 1 BOX		
1	NDC:62646-AS3-PO	3 in 1 POUCH		
1	NDC:62646-AS3-92	110 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA820915	02/01/2012	

Labeler - Medsep Corporation (928224765)

Registrant - Medsep Corporation (928224765)

Establishment

Name	Address	ID/FEI	Business Operations
Medsep Corporation		928224765	manufacture, relabel, repack

Revised: 1/2012

Medsep Corporation