STERILE CORD BLOOD COLLECTION UNIT - cord blood collection unit solution
Medsep Corporation

Sterile Cord Blood Collection Unit
Code 791-08

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION (CPD)

Sterile, non-pyrogenic fluid path. Sterilized by steam.

Rx only.

This product is free of natural rubber latex.

INDICATIONS AND USAGE

For collection of up to 210 ml of umbilical cord blood. Use aseptic technique.

Sterile Exterior

Contents inside overwrap pouch, within the foil envelope, are sterile and acceptable for use in a sterile field if pouch is unopened and undamaged; visual inspection to confirm the integrity of overwrap pouch should be performed.

WARNINGS

Do not irradiate collected cord blood or components.

Making multiple punctures of the umbilical cord to increase collection volume may increase the risk of contamination.

GENERAL PRECAUTIONS

Do not use if the package is damaged or seal is incomplete. Use only if solution is clear.

Sealing should be done in a manner that avoids fluid splatter.

Always dispose of blood-contaminated products in a manner consistent with established BIOHAZARD safety procedures.

HOW SUPPLIED

The Collection Unit inside the overwrap pouch, within the foil envelope, are sterile and acceptable for use in a sterile field if pouch is unopened and undamaged.

INFORMATION FOR PATIENTS

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

DonorCare is a registered trademark of ITL Corporation, Canberra, Australia. Produced under license from ThermoGenesis Corp.

Instructions for Use

1. Ensure DonorCare® Needle Guard (DCNG) is positioned on the tubing between the needle hub and Pinch Clamp. Engage Pinch Clamp. Ensure tethered cap is placed securely on the air vent.

2. Using aseptic technique, insert needle into umbilical vein, disengage Pinch Clamp to collect cord blood, mixing frequently, according to standard procedures.

3. Upon completion of collection, engage Pinch Clamp then withdraw needle from umbilical vein. Slide the DCNG midway over the needle hub. While holding the sides of DCNG near front, grasp tubing and pull smoothly, pulling needle into the DCNG until it locks into place. Confirm that needle is locked by listening for the second click as the needle is drawn into the DCNG. Ensure that tubing cannot be pulled through DCNG.

4. Place the bag on a work surface. While holding the tubing above the bag, open the tethered cap on the air vent. Allow the blood to drain from the tubing into the bag.

5. When the tubing has been drained, hold tubing vertical and seal tubing directly below the Y-piece with air vent.

6. Detach and discard needle, DCNG, Pinch Clamp, Air Vent and tubing according to standard procedures.

7. Determine amount of anticoagulated blood collected. If required, add sedimenting agent to CPD anticoagulated blood through Sample Port using a syringe according to standard procedures.

8. Mix well. Take care to strip and mix any blood in tubing.

9. Load bag into centrifuge cup. It is suggested that a means of support is used to prevent bag from collapsing and to reduce wrinkles.

10. Centrifuge according to standard procedures to obtain mononuclear cell-rich plasma.

BAG LABEL

Collection Bag Label

HPC, Cord Blood

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION

35 ml Anticoagulant Citrate Phosphate Dextrose Solution for collection of up to 210 ml of umbilical cord blood. Each 35 ml of CPD solution contains 0.921 g sodium citrate (dihydrate), USP; 0.893 g dextrose (monohydrate), USP; 0.114 g citric acid (monohydrate), USP; and 0.078 g monobasic sodium phosphate (monohydrate), USP. Use only if solution is clear.

Warning: This product may transmit infectious agents. Sterile, nonpyrogenic fluid path. Do not irradiate. **Rx only.**

Code 791-08

Issued August 2010, 147791082

STERILE CORD BLOOD COLLECTION UNIT cord blood collection unit solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62646-791
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CITRATE (UNII: 1Q73Q2JULR) (CITRIC ACID - UNII:2968PHW8QP)	SODIUM CITRATE	0.921 g in 35 mL
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (DEXTROSE - UNII:IY9XDZ35W2)	DEXTROSE MONOHYDRATE	0.893 g in 35 mL
CITRIC ACID (UNII: 2968PHW8QP) (CITRIC ACID - UNII:2968PHW8QP)	CITRIC ACID	0.114 g in 35 mL
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) (PHOSPHORIC ACID - UNII:E4GA8884NN)	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	0.078 g in 35 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:62646-791-08	35 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA800222	03/16/2011	

Labeler - Medsep Corporation (928224765)

Registrant - Medsep Corporation (928224765)

Establishment

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

Revised: 3/2011 Medsep Corporation