PALL STERILE CORD BLOOD COLLECTION UNIT- sterile cord blood collection unit solution
Haemonetics Corporation

Sterile Cord Blood Collection Unit

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION (CPD)

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

This product is free of natural rubber latex.

Indications and Usage Section

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

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 Section

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

Do not irradiate collected cord blood or components.

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

Visit us at www.pall.com/medical

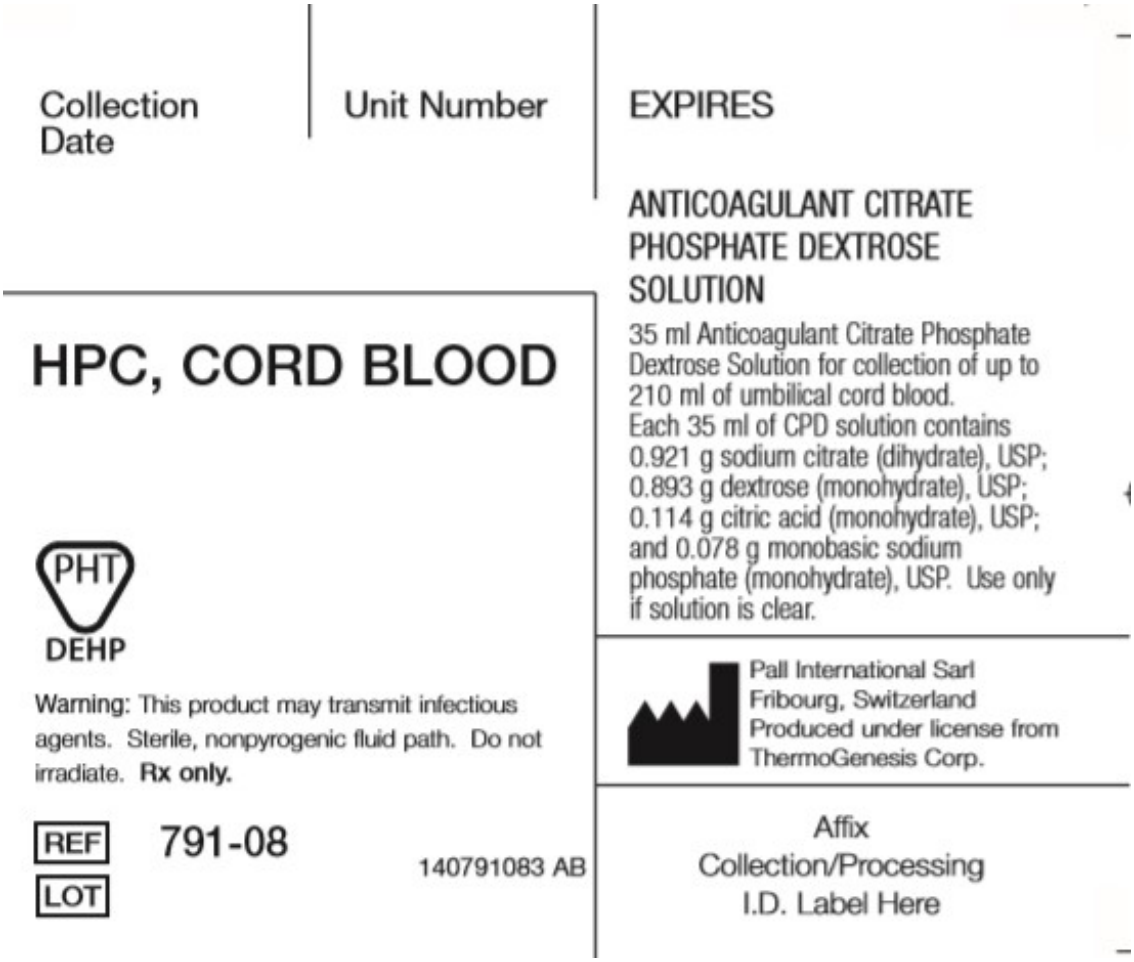
For Pall customer service, call: 1.800.645.6578

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

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.



PALL Medical

STERILE CORD BLOOD COLLECTION UNIT

Anticoagulant Citrate Phosphate Dextrose Solution (CPD)
For collection of up to 210 ml of umbilical cord blood

Each unit consists of collection bag with 35 ml of CPD solution.
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.
Rx only. Sterile, nonpyrogenic fluid path. Sterilized by steam.
See accompanying directions for use. Store at room temperature.

Collection unit inside overwrap pouch, within this foil envelope is sterile and acceptable for use in sterile field if over wrap pouch is unopened and undamaged; inspect for integrity.

Discard foil envelope.

1 Unit

Code 791-08

Manufactured for:
Pall International Sàrl
Avenue de Tivoli 3
CH-1700 Fribourg
Switzerland

PHT
DEHP

LOT 0000000

0000-00 #

Produced under license from ThermoGenesis Corp.
151791084 AC

PALL Medical

LOT ######

24 Units YYYY-MM #

STERILE CORD BLOOD COLLECTION UNIT

Anticoagulant Citrate Phosphate Dextrose Solution (CPD)
For collection of up to 210 ml of umbilical cord blood Rx only.
Sterile, nonpyrogenic fluid path. Sterilized by steam.
See accompanying directions for use. Store at room temperature.
Avoid excessive heat. Protect from freezing.

Manufactured for:
Pall International Sàrl
Avenue de Tivoli 3
CH-1700 Fribourg
Switzerland

Produced under license from ThermoGenesis Corp.
152791083 AB

Code 791-08

PHT
DEHP

[Insert Barcode Here]

(01)30636207307966(30)24(17)YYMMDD(10)#######

PALL Medical

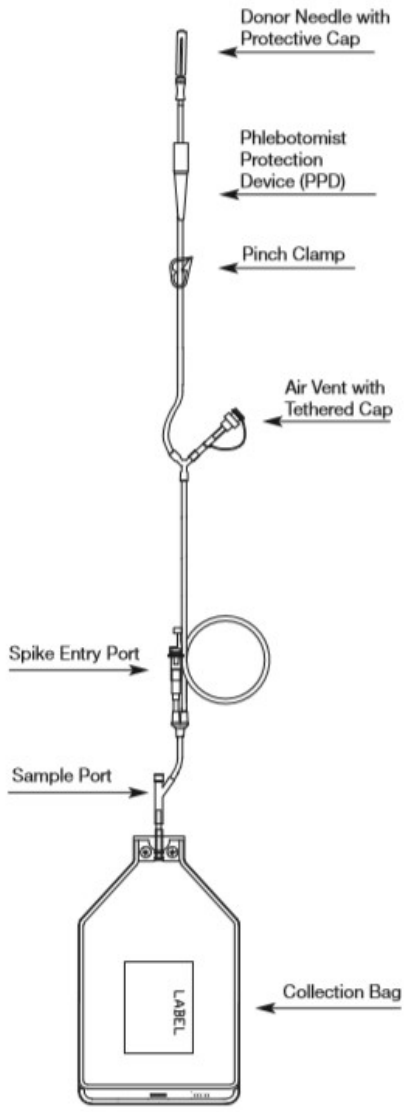
PHT DEHP

Manufactured for:
Pall International Sarl
Avenue Tivoli 3
CH-1700 Fribourg
Switzerland
www.pall.com/medical
For customer service,
call: 1.800.645.6578

REF **791-08**

Sterile Cord Blood Collection Unit

Anticoagulant Citrate Phosphate Dextrose Solution (CPD)



For collection of up to 210 ml of umbilical cord blood. Use aseptic technique. Collection unit inside overwrap pouch, within the foil envelope, is sterile and acceptable for use in a sterile field if overwrap pouch is unopened and undamaged; visual inspection to confirm the integrity of overwrap pouch should be performed. Do not use if the package is damaged or seal is incomplete. Precaution: Use only if solution is clear. Sterile, nonpyrogenic fluid path. Sterilized by steam. **Rx only. Note:** This product is not made with natural rubber latex. Discard foil envelope.

Instructions for Use

1. Ensure Phlebotomist Protection Device (PPD) 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. **Note:** Making multiple punctures of the umbilical cord to increase collection volume may increase the risk of contamination.
3. Upon completion of collection, engage Pinch Clamp then advance PPD over the needle hub. Hold the PPD just below the taper. Grasp the tubing below the PPD and pull the needle into the PPD with a continuous motion until the needle is completely withdrawn and secured into place.
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, PPD, 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.

Note: Do not irradiate collected cord blood or components.

* 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.

147791085 AC, issued Aug. 2019

PALL STERILE CORD BLOOD COLLECTION UNIT

sterile cord blood collection unit solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53157-791
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	0.893 g in 35 mL
SODIUM CITRATE (UNII: 1Q73Q2JULR) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	SODIUM CITRATE	0.921 g in 35 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	0.114 g in 35 mL
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	0.0078 g in 35 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	35 g in 35 mL
PHOSPHORIC ACID (UNII: E4GA8884NN)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53157-791-01	35 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	BN800222	03/16/2011	

Labeler - Haemonetics Corporation (057827420)

Establishment

Name	Address	ID/FEI	Business Operations
Haemonetics Manufacturing Inc.		078598396	manufacture(53157-791)

Revised: 6/2020 Haemonetics Corporation