

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

Global Life Sciences Solutions USA LLC

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.



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



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

REF

791-08

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Medical



Fabriqué pour:
Pall International Sari
Avenue de Tivoli 3
CH-1700 Fribourg
Switzerland
www.pallmedical.com

Pour le service à la clientèle,
www.cytiva.com/contact

REF

791-08

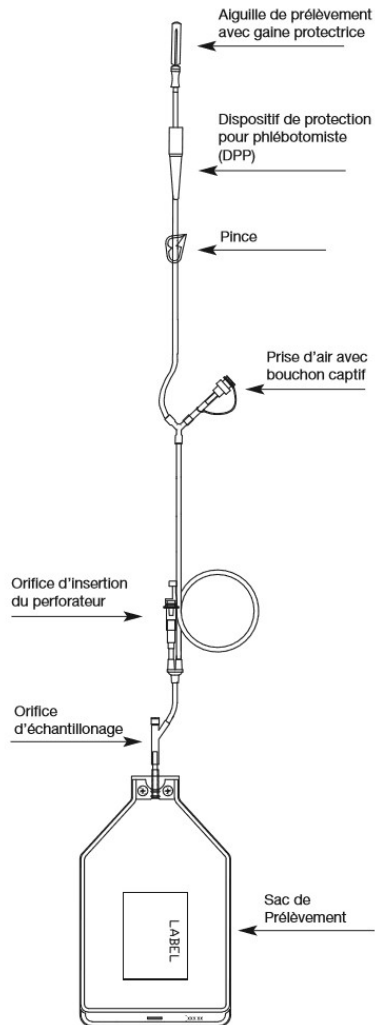
Unité de prélèvement de sang de cordon stérile

Solution anticoagulante de citrate, de phosphate et de dextrose (CPD)

Destiné au prélèvement de jusqu'à 210 ml de sang de cordon ombilical. Utiliser sous asepsie. L'unité de prélèvement de la poche enveloppante, à l'intérieur de l'enveloppe de papier aluminé, est stérile et peut être utilisée dans un champ stérile si la poche enveloppante n'est ni ouverte ni abîmée; une inspection visuelle confirmant l'intégrité de la poche enveloppante devrait donc être effectuée.

Ne pas utiliser si l'emballage est abîmé ou que le joint est incomplet.

Précaution: N'utiliser que si la solution est limpide. Circuit de solution apyrogène stérile. Stérilisé à la vapeur. **Sur ordonnance seulement.** Note: Ce produit n'est pas constitué de latex de caoutchouc naturel. Jeter l'enveloppe de papier aluminé.



Mode d'emploi

- Vérifier que le dispositif de protection pour phlébotomiste (DPP) est en place sur la tubulure entre le manchon de l'aiguille et la pince. Serrer la pince. Vérifier que le bouchon captif est solidement monté sur la prise d'air.
 - Sous asepsie, insérer l'aiguille dans la veine du cordon et dégager la pince afin de prélever le sang de cordon, en mélangeant fréquemment, conformément aux procédures en vigueur.
Note: Les ponctions multiples du cordon ombilical visent à augmenter le volume de prélèvement risquent d'accroître le risque de contamination.
 - Une fois le prélèvement terminé, resserrer la pince et ensuite placer le DPP sur le manchon de l'aiguille. Tenir le DPP sur la portion cintrée. Saisir la tubulure sous le DPP et dans un mouvement fluide et continu, tirer l'aiguille de prélèvement dans le DPP jusqu'à qu'elle soit complètement retirée et sécurisée en place.
 - Placer le sac sur une surface de travail. En tenant la tubulure au-dessus du sac, ouvrir le bouchon captif de la prise d'air. Laisser le sang s'écouler de la tubulure vers le sac.
 - Une fois la tubulure vide, la tenir à la verticale et la souder directement sous le raccord en Y muni de la prise d'air.*
 - Détacher et jeter l'aiguille, le DPP, la pince, la prise d'air et la tubulure conformément aux procédures en vigueur.*
 - Déterminer la quantité prélevée de sang traité à l'anticoagulant. Au besoin, ajouter un agent de sédimentation au sang traité au CPD au moyen d'une seringue par l'orifice d'échantillonnage, en respectant les procédures en vigueur.
 - Bien mélanger. Prendre soin de déloger (stripper) et de mélanger tout sang présent dans la tubulure.
 - Installer le sac dans la centrifugeuse. L'utilisation d'un support est recommandé afin d'empêcher le sac de s'affaisser et de réduire la formation de plis.
 - Centrifuger conformément aux procédures en vigueur afin d'obtenir un plasma riche en cellules mononucléaires.
- Note:** Ne pas irradier le sang de cordon prélevé ni les composants.
- * Durant la procédure, prendre en tout temps les précautions suivantes:
- Sceller de façon à éviter les éclaboussures.
 - Toujours se débarrasser des composants sanguins conformément aux règlements en matière de déchets **BIOMÉDICAUX**.

PALL est une marque déposée de Pall Corporation.



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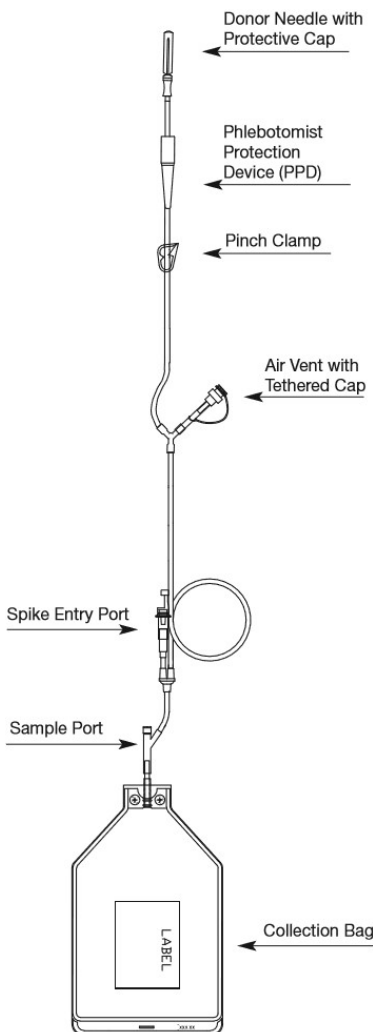
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www.pallmedical.com
For customer service,
www.cytiva.com/contact

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.

PALL is a registered trademark of Pall Corporation.

 Medical

LOT 0000000

24 Units

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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



REF 791-08

152791083 AC



(01)30636207307966(30)24(17)000000(10)000000

Bag label.jpg

Collection Date	Unit Number	EXPIRES
<p>HPC, CORD BLOOD</p>  <p>Warning: This product may transmit infectious agents. Sterile, nonpyrogenic fluid path. Do not irradiate. Rx only.</p>		<p>ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION</p> <p>35 ml Anticoagulant Citrate Phosphate Dextrose Solution for collection of up to 210 ml of umbilical cord blood.</p> <p>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.</p>
		 <p>Pall International Sàrl Fribourg, Switzerland</p>
<p>REF 791-08</p> <p>LOT</p>	<p>140791083 AC</p>	<p>Affix Collection/Processing I.D. Label Here</p>

sterile cord blood collection unit solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:79403-791
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:79403-791-01	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 - Global Life Sciences Solutions USA LLC (011658242)

Establishment

Name	Address	ID/FEI	Business Operations
Haemonetics Manufacturing Inc.		078598396	manufacture(79403-791)