



## User Guide for the 791-08 Sterile Cord Blood Collection Unit

### Introduction

The User Guide for Pall's Sterile Cord Blood Collection Unit (791-08) is specifically designed to assist customers with training and implementation. The information contained herein may be used for the development of appropriate documentation including sample Standard Operating Procedures and documents to facilitate staff training. The document should not be used

as a stand alone document to address specific regulatory requirements of the hospital or blood processing center. Further information on collection and processing of cord blood can be found on the Cord Blood Transplantation Study (COBLT) website at: <https://web.emmes.com/study/cord/default.htm>.

### Overview

The 791-08 Sterile Cord Blood Collection Unit is for the collection of up to 210 mL of umbilical cord blood. It is packaged so that the contents are sterile and therefore suitable for use in a sterile surgical field. **The collection unit is appropriate for use in any cord blood collection setting including cesarean section, vaginal birth, or ex utero cord blood collection. There is no need for additional extension sets or assembly at time of collection.**

The 791-08 is based on the well-established Pall 791-01 Cord Blood Collection Bag, but has a number of additional features that are unique to Pall. These features include:

- Custom packaging and a tailored sterilization process for the set which has cleared the FDA as suitable for use in a sterile surgical field.
- Anticoagulant type and volume are specifically selected for cord blood collection to ensure a robust and easy-to-use process.
  - Pre-filled with 35 mL of Citrate Phosphate Dextrose (CPD) anticoagulant.
  - This anticoagulant volume permits collection of up to 210 mL of cord blood; suitable for the largest collections.

- A tapered-wall collection bag shape that maximizes both the recovery and the consistency of recovery of cell-rich plasma.
- An in-line sterile air vent that permits the recovery of cord blood without the need to strip the tubing which can lead to cell damage. The tethered cap on the vent ensures that there are no loose parts in the sterile field.
- An in-line DonorCare™ Needle Guard for the prevention of needle stick injuries.
- In-line spike entry port that permits easy spike connection of processing sets such as Pall's 791-02.
- Tubing diameter that is compatible with sterile connection devices.
- A multi-use sampling port permits sample collection for testing and facilitates the addition of solutions such as sedimenting agents if desired.

## Set Components and Descriptions

- A. Donor Needle with Protective Cap** is an ultra-thin walled 16-gauge donor needle with a tamper evident needle cover and a finger-contoured hub for a secure and comfortable grip. Needle sharpness is 100% tested to ensure easy access.
- B. DonorCare Needle Guard (DCNG)\*** is pre-attached on the tubing leading to the donor needle. The DCNG is used to enclose the donor needle after collection to reduce the potential for needle stick injury.
- C. Pinch Clamp** is provided to close off the tubing after the collection is complete.
- D. Air Vent with Tethered Cap** maximizes cord blood collection by allowing sterile air to enter the set and drain the tubing. The tether keeps the cap attached to the set to avoid loss.

- E. Collection Set Tubing** is compatible with sterile connection devices. **Note:** The section between the air vent and the spike entry port should be used for tying knots (if desired).
- F. Spike Entry Port** is provided for subsequent access of cord blood processing sets like the Pall 791-02.
- G. Sample Port** can be accessed to collect samples or add solutions that facilitate processing of the cord blood.
- H. Collection Bag** is designed to maximize cell recovery through its unique tapered top shape.

\*For more information about the DCNG, refer to the manufacturer's (ITL) instructions for use.



791-08 Cord Blood Collection Bag

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## Collection Procedures

To prepare for collection of umbilical cord blood, the 791-08 should enter the sterile surgical field as per standard procedures.

### USE APPROPRIATE ASEPTIC TECHNIQUE

1. Open the 791-08 external foil pouch and remove the peel pouch outside of the sterile surgical field.
2. Open the peel pouch to release the 791-08 bag set into the sterile surgical field.
3. Discard both external foil bag and peel pouch.

### Vaginal Birth after the delivery of the baby and the umbilical cord is cut.

1. Prepare the umbilical cord for venipuncture as per standard procedures.
2. Obtain the 791-08 and inspect the set to ensure that the DCNG is between the clamp and the donor needle and that the cap is securely placed on the air vent.
3. Close the pinch clamp.
4. Remove the needle cover by twisting to break the seal and then remove in a smooth, straight motion.
5. Insert the needle into the umbilical vein and open the clamp.
6. Lower the bag and by gravity flow collect as much cord blood as possible. **Note:** Lowering the bag to full extension will increase the flow rate. The collection should take approximately 3-5 minutes. Mix the anticoagulant and cord blood frequently during collection to avoid clotting.
7. Close pinch clamp when blood flow has stopped.
8. Withdraw the needle from the umbilical cord and align the finger contours of the needle hub so that they are parallel to the opening of the DCNG.
9. Slide the DCNG midway over the needle hub.
10. While holding the sides of the DCNG, grasp the tubing and pull smoothly to draw the needle into the DCNG and lock into place.
11. Confirm that the needle is locked by listening for the second click as the needle is drawn into the DCNG. Ensure the tubing cannot be pulled through the DCNG.
12. Place the collection bag on a work surface and fully extend the tubing above the bag.
13. Remove the tethered cap from the air vent. Allow the blood within the tubing to drain into the bag.
14. Seal tubing directly below Y piece with the air vent.
15. Detach and discard the tubing assembly containing the DCNG, pinch clamp and air vent.
16. Prepare set for shipment to the Cord Blood Processing Center.

### Cesarean/Sterile Procedure after delivery of the baby and the umbilical cord is cut.

**Note:** The 791-08 is packaged to be suitable for use in the sterile surgical field.

1. Prepare the umbilical cord for venipuncture as per standard procedures.
2. Obtain the 791-08 and inspect the set to ensure that the DCNG is between the clamp and the donor needle and that the cap is securely placed on the air vent.
3. Close the pinch clamp.
4. Remove the needle cover by twisting to break the seal and then remove in a smooth, straight motion.
5. Insert the needle into the umbilical vein and open the clamp.
6. Lower the bag and by gravity flow collect as much cord blood as possible. **Note:** Lowering the bag to full extension will increase the flow rate. The collection should take approximately 3-5 minutes. Mix the anticoagulant and cord blood frequently during collection to avoid clotting.
7. Close pinch clamp when blood flow has stopped.
8. Withdraw the needle from the umbilical cord and align the finger contours of the needle hub so that they are parallel to the opening of the DCNG.
9. Slide the DCNG midway over the needle hub.
10. While holding the sides of the DCNG, grasp the tubing and pull smoothly to draw the needle into the DCNG and lock into place.
11. Confirm that needle is locked by listening for the second click as the needle is drawn into the DCNG. Ensure the tubing cannot be pulled through the DCNG.
12. Place the collection bag on a work surface and fully extend the tubing above the bag.
13. Remove the tethered cap from the air vent. Allow the blood within the tubing to drain into the bag.
14. Seal tubing directly below Y piece with the air vent.
15. Detach and discard the tubing assembly containing the DCNG, pinch clamp and air vent.
16. Prepare set for shipment to the Cord Blood Processing Center.

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## Collection Procedures *(continued)*

**Umbilical Cord Blood in an Ex Utero Procedure** after the delivery with the umbilical cord cut and the placenta is delivered and placed in a sterile basin to be provided to the collector.

1. Place the placenta fetal side down into a chux pad which has been attached to the collection stand.
2. Punch a hole in the middle of the chux pad and then pull the cord through.
3. Prepare the umbilical cord for venipuncture as per standard procedures. **Note:** To assist in the collection, it is recommended to use a metal hemostat below the cord clamp. This will allow the cord to be held taut during collection.
4. Prepare the umbilical cord for venipuncture as per standard procedures.
5. Obtain the 791-08 and inspect the set to ensure that the DCNG is between the clamp and the donor needle and that the cap is securely placed on the air vent.
6. Close the pinch clamp.
7. Remove the needle cover by twisting to break the seal and then remove in a smooth, straight motion.
8. Insert the needle into the umbilical vein and open the clamp.
9. Lower the bag and by gravity flow collect as much cord blood as possible. **Note:** Lowering the bag to full extension will increase the flow rate. The collection should take approximately 3-5 minutes. Mix the anticoagulant and cord blood frequently during collection to avoid clotting.
10. Close pinch clamp when blood flow has stopped.
11. Withdraw the needle from the umbilical cord and align the finger contours of the needle hub so that they are parallel to the opening of the DCNG.
12. Slide the DCNG midway over the needle hub.
13. While holding the sides of the DCNG, grasp the tubing and pull smoothly to draw the needle into the DCNG and lock into place.
14. Confirm that needle is locked by listening for the second click as the needle is drawn into the DCNG. Ensure the tubing cannot be pulled through the DCNG.
15. Place the collection bag on a work surface and fully extend the tubing above the bag.
16. Remove the tethered cap from the air vent. Allow the blood within the tubing to drain into the bag.
17. Seal tubing directly below Y piece with the air vent.
18. Detach and discard the tubing assembly containing the DCNG, pinch clamp and air vent.
19. Prepare set for shipment to the Cord Blood Processing Center.

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.

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## Processing Procedures

**Note:** Centrifugation parameters will need to be assessed and validated by the Cord Blood Processing Center to ensure maximum cell recovery.

1. Weigh the CPD anticoagulated cord blood to determine amount collected.
2. If required, add sedimenting agent to the cord blood through the Y injection site using a syringe according to standard operating procedures.
3. Mix the unit well.
4. Take care to strip any blood from the tubing into the bag and mix well. **Note:** To empty the tubing during stripping, strip the tubing to the port of the bag and keep the strippers closed. Hold the tubing upright above the bag then open the strippers.
5. Load the bag into the centrifuge cup. It is suggested that a means of support is used to prevent the bag from collapsing and to reduce wrinkles.
6. Balance the centrifuge cups.
7. Centrifuge as per standard operating procedures to obtain cell-rich plasma.



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