



## Frequently Asked Questions

### 791-08 Cord Blood Sterile Collection Bag

#### Introduction

Cord blood banks have traditionally used two types of collection models. One model employs the use of an obstetrician or midwife to perform the collection during the third stage of labor. The second method is performed by a cord blood bank staff member who receives the placenta after it has been delivered and brings it into a separate room to perform the collection. With the growing number of cesarean section deliveries, the need arose to perform the harvest in a sterile surgical field. The only bags previously available did not have a sterile exterior and thus were not able to be used in these situations. The most common option available was to use a sterile extension set that needed to be assembled and then placed in the sterile field so that the collection bag remained outside of that field. Pall Corporation has subsequently manufactured a Cord Blood Sterile Collection Bag that has a sterile exterior that can be used during vaginal or cesarean collections and requires no extra manipulations during the collection.

#### 1. What methods/tools can be employed to maintain the integrity of the sterile field while collecting cord blood during a cesarean delivery?

The Pall Cord Blood Sterile Collection Bag can be used during vaginal or cesarean section deliveries because both the fluid path and the exterior are sterile.

Alternatively, a sterile extension set can be used that is placed in the sterile field and connected to a collection bag with a non-sterile exterior.

- This requires some assembly and raises safety concerns for the staff and the product.

- The collection bag needle must pierce the injection adapter thus creating a risk of needle stick injuries to staff.
- There is also a risk of puncturing the extension tubing with the collection bag needle.

#### 2. What is a sterile fluid path?

Bags available for cord blood harvests are sterile on the interior of the bag where the blood comes in contact with the bag. This DOES NOT necessarily mean that the exterior of the bag is sterile.

#### 3. What is a sterile exterior and why is it important?

A sterile exterior allows the collection bag to be placed into a surgical field without adding risk of contamination from the exterior of the collection bag.

Cord blood collected during a cesarean section occurs in a sterile surgical environment. Bags without a sterile exterior CANNOT be placed into the sterile field without the use of sterile extension sets which require assembly and subsequent connection to the collection bag. Pall's Cord Blood Sterile Collection Bag can be placed directly into this field. Collection staff can use this bag during vaginal or cesarean section harvests, eliminating the need for additional parts such as extension sets. This eliminates the need to use different supplies for vaginal and cesarean section collections. Because the Pall sterile collection bag was designed to be used in a sterile field, its packaging is also configured for ease of use in a surgical field.

#### 4. What other features does the Pall Cord Blood Sterile Collection Bag have?

The Pall Cord Blood Sterile Collection Bag not only has a sterile fluid path but also a sterile exterior. Pall uses an innovative packaging and sterilization/pasteurization process so that it may be placed directly into a sterile surgical field. Because this bag was designed specifically for cord blood harvests, Pall also incorporated the following:

- A DonorCare® needleguard which guards against accidental needle sticks to collection staff.
- A sterile air vent so that the cord blood can be safely drained into the collection bag without risk of contamination by room air.
  - There is also no mechanical damage from “stripping” the tubing to force the cord blood in the tubing to be drained into the collection bag.
  - After collection of the umbilical cord blood, the ability for collection staff to drain the cord blood into the collection bag in a sterile manner will reduce the chance of clotting in the tubing.
- A multiple use sampling port so that samples can be extracted and solutions (i.e. Hydroxyethyl Starch) can be added without the need for the insertion of a sampling site coupler.
- An in-line spike entry port permits the connection to other processing systems.
- Tubing that is compatible for use with sterile connection devices.
- A needle which contains a finger-friendly contoured hub with a “bevel up” indicator to facilitate the needle insertion into the umbilical vein.

#### 5. Why do I sometimes see moisture on the surface of the internal packaging?

The Pall Cord Blood Sterile Collection Bag undergoes a sterilization/pasteurization process. Therefore, you may see moisture on the interior of the foil packaging or on the sterilization pouch. This DOES NOT compromise the sterility or function of the bag.

#### 6. What is the Regulatory Status of the Pall Cord Blood Sterile Collection Bag?

- FDA NDA approved
- CE marked under the Medical Devices Directive
- Approved for sale in accordance with the Canadian Medical Device Regulations

#### 7. Is the Pall Cord Blood Sterile Collection Bag compatible with various manual or automated processing sets for subsequent downstream processing?

The design of the Pall Cord Blood Sterile Collection Bag provides options for connection to the processing sets:

- The spike port on the collection bag allows direct connection to any processing set that has tubing with a spike end.
- The tubing on the collection bag can be connected to any processing set with standard blood tubing using a sterile connecting device.



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