PALL Medical

Cord Blood Collection, Processing and Freezing Bag Sets

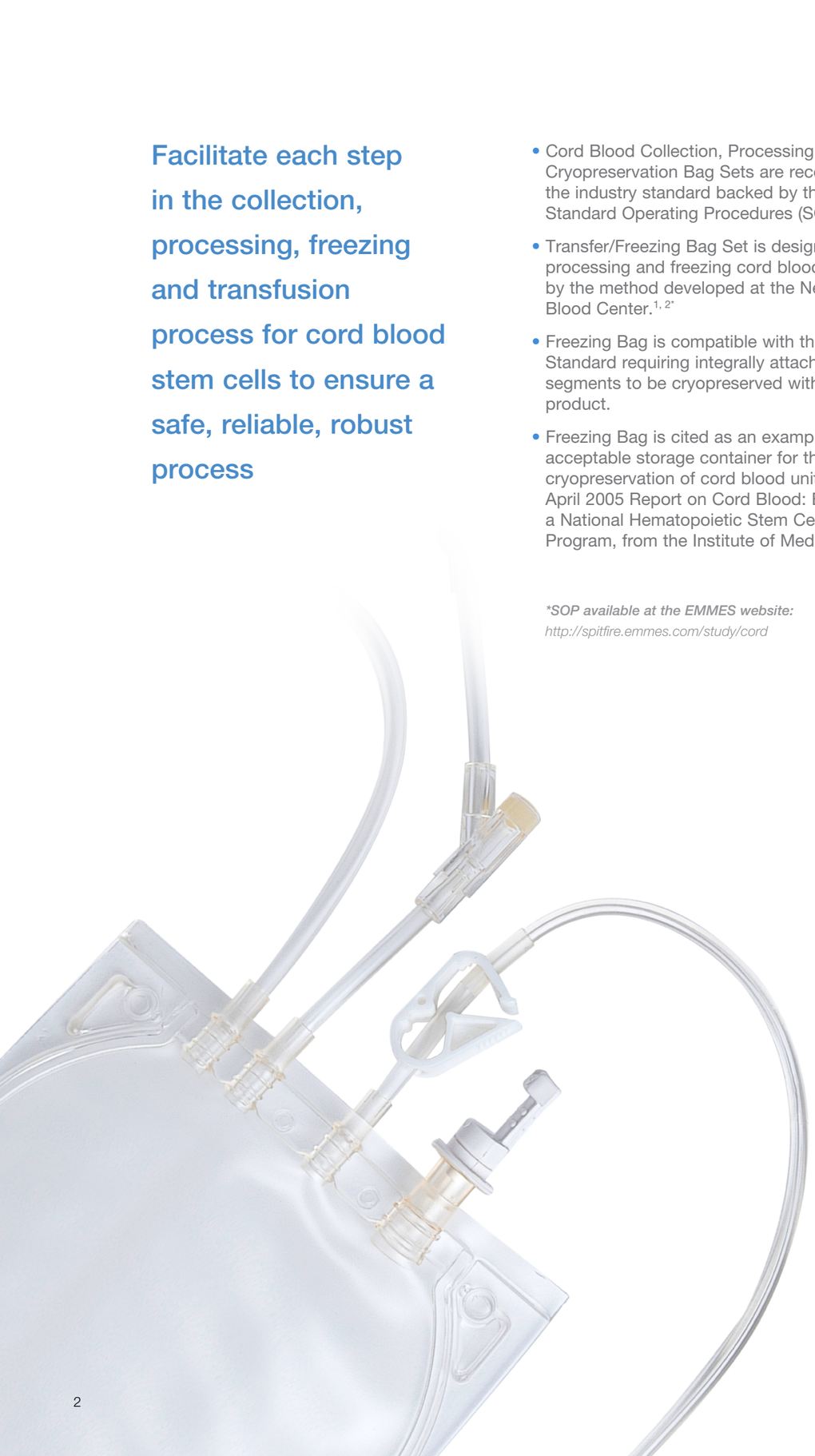
for the Cryopreservation of Blood and Cellular Components

Protect What Matters - Every Day

Facilitate each step in the collection, processing, freezing and transfusion process for cord blood stem cells to ensure a safe, reliable, robust process

- Cord Blood Collection, Processing and Cryopreservation Bag Sets are recognized as the industry standard backed by the CoBLT Standard Operating Procedures (SOP).[1, 2*]
- Transfer/Freezing Bag Set is designed for processing and freezing cord blood stem cells by the method developed at the New York Blood Center.[1, 2*]
- Freezing Bag is compatible with the AABB Standard requiring integrally attached segments to be cryopreserved with the product.
- Freezing Bag is cited as an example of an acceptable storage container for the cryopreservation of cord blood units in the April 2005 Report on Cord Blood: Establishing a National Hematopoietic Stem Cell Bank Program, from the Institute of Medicine.[3]

**SOP available at the EMMES website:*
http://spitfire.emmes.com/study/cord



Advanced Bag Designs Meet Rigorous Industry Standards

Cord blood stem cells have been effectively used in the treatment of more than 70 malignant and non-malignant diseases, including sickle cell, leukemia, non-Hodgkin's lymphoma, other forms of cancer, life-threatening anemias, and autoimmune diseases. As a key supplier to the cord blood banking industry, Pall provides a full range of bag sets that are used to prepare the cord blood stem cells for treatment.

Pall's advanced freezing bag design divides the sample into two compartments, enabling a 4:1 division of sample for ex vivo cell expansion.

Pall's collection and processing sets are manufactured to cGMP using validated manufacturing processes that ensure safe, consistent and reliable product performance. Each bag is 100% inspected prior to release and is fully traceable by lot number.

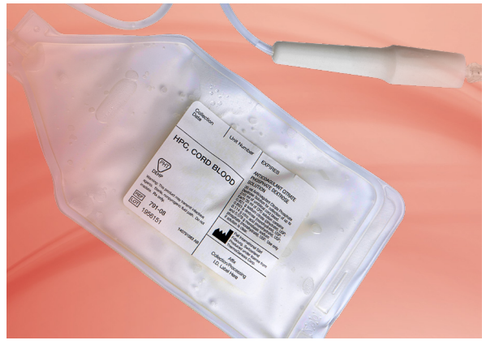
Pall's bag sets are uniquely designed to facilitate closed system processing of cord blood stem cells by the volume reduction method developed at the New York Blood Center.[1] Volume reduction maximizes limited storage space while closed system processing minimizes sample loss and reduces the risk of contamination during handling. This method results in a high quality sample available for transplantation. SOP's referencing Pall bag sets are available at the EMMES website: http://spitfire.emmes.com/study/cord[1]

Assessment of stem cell content and viability after long-term storage is a critical step prior to a successful transplantation. International standards recommend storing a cell sample attached to a unit of cord blood for quality control testing. Pall's freezing bag includes sufficient tubing for the preparation of segments, enabling a sample aliquot to be cryopreserved with the final product. Using a tube segment for quality control testing prior to transplantation reduces the risk of contamination during the thawing process and provides critical information needed to predict treatment success.

For disease treatments or patient populations that require a higher cell dose to be transplanted, Pall's advanced freezing bag design divides the sample into two compartments, facilitating transfusion of 80% of the stem cells while retaining 20% of the stem cells for ex vivo cell expansion. Scientific advances in our ability to amplify stem cells will greatly expand the applications for hematopoietic stem cells from cord blood.

Cord Blood Sterile Collection Bag

America Part Number: 791-08



For the collection of umbilical cord blood from either a vaginal birth or within the sterile field of a cesarean section.

- Anticoagulant type and volume are specifically selected for cord blood collection to ensure a robust and easy-to-use process:
  - Bag with 250 mL fill volume
  - Set contains 35 mL of Citrate Phosphate Dextrose (CPD) anticoagulant
  - Permits the collection of up to 210 mL of cord blood
- Innovative packaging and the sterilization process result in a collection bag that can be used safely within the sterile surgical field.
- Unique collection bag shape maximizes the recovery of cell-rich plasma.
- The in-line sterile air vent permits the recovery of blood without the need to strip tubing; a process that can lead to cell damage. The tethered cap on the vent ensures that there are no loose parts in the sterile field.
- Needle contains a finger-friendly contoured hub with a “bevel up” indicator to facilitate a secure needle stick into the umbilical vein.
- DonorCare Needleguard is a simple but effective method for protecting against accidental needle-stick injuries to collection staff.
- In-line spike entry port/tubing is compatible with sterile connection devices. This permits connection to other blood processing components by any preferred means. It also provides a back-up system for sterile connection device failure or lack of availability.
- Multiple-use sampling port permits sample for testing and facilitates the addition of solutions such as sedimenting agents.

Transfer/Freezing Bag Set

America Part Number: 791-02
Europe Part Number: 791-02U

For processing and freezing 25 mL of cryopreserved, concentrated cord blood stem cells by the method developed at the New York Blood Center.[1, 2*] Each sterile set consists of two transfer bags and a two-compartment, three-dimensional 25 mL freezing bag joined by integral tubing and two connector lines (one spike and one luer).

- Two transfer bags, 200 and 150 mL. The 200mL transfer bag concentrates primary stem cell-rich plasma while the 150 mL transfer bag receives the supernatant plasma from the concentrated stem cells.[1, 2*]
- Freezing bag is compatible with liquid nitrogen (LN2) storage. The three-dimensional bag design ensures a homogenous, controlled freezing rate for maximum cell viability.
- Freezing bag is uniquely compatible with the use of DMSO/Dextran and liquid nitrogen storage in ThermoGenesis Corporation’s BioArchive◆ System.
- Freezing bag’s two separable compartments allow for a 4:1division of contents, allowing a consistent volume aliquot for ex vivo cell expansion.
- Freezing bag is compliant with AABB Standard for integral segments cryopreserved with product, enabling confirmatory testing prior to transfusion.
- Addition of cryopreservative solution can be accomplished by either gravity feed or syringe pump.

SOP available at the EMMES website:
http://spitfire.emmes.com/study/cord

Cell Wash/Infusion Bag Set

America Part Number: 791-03
Europe Part Number: 791-03U

For the thaw/washing and subsequent infusion of previously frozen cord blood stem cells as developed by the New York Blood Center.[1, 2*] This two-bag set is designed to achieve a slow asymptotic reduction in osmotic pressure of the cryoprotected white cells to the appropriate level for transfusion. Set reduces the DMSO content of the final stem cell transfusion to less than one gram. Each sterile set consists of two transfer bags joined by integral tubing, and three connector lines (two spikes and one luer).

- Designed specifically for use with the freezing bag of the Transfer/Freezing Bag Set (PN 791-02) and the Freezing Bag (PN 791-05). Components include:
  - Two 250 mL capacity transfer bags. One 250 mL transfer bag is used for thawing the frozen unit with a Dextran/albumin solution. The second 250 mL transfer bag receives supernatant from the concentrated stem cells.[1, 2*]
  - Two multiple-use sampling sites.

SOP available at the EMMES website:
http://spitfire.emmes.com/study/cord

Freezing Bag

America Part Number: 791-05
Europe Part Number: 791-05U

For the long-term storage of 25 mL of cryopreserved, concentrated blood components. Each sterile set consists of a two-compartment, three-dimensional 25 mL freezing bag and a tubing lead terminating in a spike. The freezing bag has been designed to assure a homogenous, controlled freezing rate for maximum cell viability. The design simultaneously reduces the possibility of bag breakage from thermal, dynamic or expansion forces.

- Freezing bag is compliant with AABB Standard for integral segments cryopreserved with product, enabling additional testing prior to transfusion.
- Two separable compartments allow for a 4:1 division of contents, allowing a consistent volume aliquot for ex vivo cell expansion.
- Compatible with liquid nitrogen (LN2) storage. Three-dimensional bag design ensures a homogenous, controlled freezing rate for maximum cell viability.
- Freezing bag is uniquely compatible with DMSO/Dextran and liquid nitrogen storage in ThermoGenesis Corporation’s BioArchive◆ System.
- Compatible with the Cell Wash/Infusion Bag Set (PN 791-03).
- Bag sold separately for connection to other processing sets.
- Tubing is RF or heat sealable.

Specification and Ordering Information

Specifications

Part Number	791-08	791-02, 791-02U	791-03, 791-03U	791-05, 791-05U
Description	Cord Blood Sterile Collection Bag	Transfer/Freezing Bag Set	Cell Wash/Infusion Bag Set	Freezing Bag
Fill Volume Range	Up to 210 mL cord blood; includes 35 mL CPD anticoagulant	Up to 200 mL in transfer bag 1; up to 150 mL in transfer bag 2; up to 25 mL in freezing bag	Up to 250 mL	Up to 25 mL
Port Configuration	(1) 16-gauge needle for venipuncture of the umbilical cord; inline spike; in-line sterile vent; multi-use sampling port	Vented needle; in-line spike; in-line luer; (2) multi-use sampling ports; (2) pinch clamps	(2) in-line spikes; in-line luer; (2) multi-use sampling ports	In-line spike
Materials of Construction	Bag, Tubing: Polyvinyl chloride (PVC)	150 and 200 mL Transfer Bag, Tubing: Polyvinyl Chloride (PVC); Freezing Bag, Tubing: Ethyl vinyl acetate	Bags, Tubing: Polyvinyl chloride (PVC)	Bags: Ethyl vinyl acetate; Tubing: Ethylene vinyl acetate and Polyvinyl Chloride (PVC)
Bag Size(s)	20.45 cm length x 11.13 cm width (8.05 in. length x 4.38 in. width)	200 mL Transfer Bag: 17.53 cm length x 11.43 cm width (6.9 in. length x 4.50 in. width); 150 mL Transfer Bag: 14.86 cm length x 7.62 cm width (5.85 in. length x 3.0 in. width); Freezing Bag: 8.84 cm length x 7.04 cm width x 0.74 cm depth (3.48 in. length x 2.77 in. width x 0.29 in. depth)	17.53 cm length x 11.43 cm width (6.91 in. length x 4.5 in. width)	8.84 cm length x 7.04 cm width x 0.74 cm depth (3.48 in. length x 2.77 in. width x 0.29 in. depth)
Sterilization	Steam	Gamma	Gamma	Gamma
Packaging	Individually packaged in an overwrap pouch inside of foil; 24/box	Individually packaged in a plastic pouch; 24/box	Individually packaged in a plastic pouch; 24/box	Four sterile bags packaged in a plastic pouch; 48/box
Shelf Life	3 years	3 years	3 years	3 years
Traceability	Lot number	Lot number	Lot number	Lot number
Regulatory Status	FDA 510(k) & NDA cleared & Canadian medical device license # 1179	791-02 is FDA 510(k) cleared 791-02U is CE marked	791-03 is FDA 510(k) cleared 791-03U is CE marked	791-05 is FDA 510(k) cleared 791-05U is CE marked
Compatible with Other Bags	N/A	791-01; 791-03	791-02; 791-05	791-03

Ordering Information

Cord Blood Collection, Processing and Freezing Bags

Part Number America	Part Number Europe	Description	Packaging
791-08	N/A	Cord Blood Sterile Exterior Collection Bag	24 units per case
791-02	791-02U	Transfer/Freezing Bag Set	24 units per case
791-03	791-03U	Cell Wash/Infusion Bag Set	24 units per case
791-05	791-05U	Freezing Bag	48 units per case

References

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