# PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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| DOCUMENT TITLE:  | Spectra Optia® Apheresis System  
Granulocyte (PMN) Collection Procedure |
| DOCUMENT NOTES:  |               |

## Document Information

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<th>Owner:</th>
<th>WATE02</th>
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PBMT-COLL-017
SPECTRA OPTIA® APERESIS SYSTEM GRANULOCYTE (PMN) COLLECTION PROCEDURE

1 PURPOSE
1.1 To describe the procedure and supplies required for granulocyte collection using the Terumo Optia Apheresis System. For information on using the Optia System, refer to the Spectra Optia® Apheresis System Operator’s Manual.

2 INTRODUCTION
2.1 The American Association of Blood Banks and Federal Drug Administration have established standards for safe collection of blood and components. These standards will be maintained during the care of all donors undergoing leukapheresis.

2.2 Bone marrow or stem cell transplant patients may become septic during the period of pancytopenia following chemotherapy. If patients are unresponsive to antibiotics, a request may be made to collect granulocytes from a related donor.

2.3 Apheresis supplies are stored at room temperature in the Stem Cell Laboratory. No supplies are kept in the apheresis room at CHC. Refer to the procedure: STCL-GEN-002 07 STCL. Supply Management Procedure.

3 SCOPE AND RESPONSIBILITIES
3.1 The apheresis technician or designee is responsible for the operation of the machine. The clinic nurse and attending physician are responsible for the care and treatment of the donor.

4 DEFINITIONS/ACRONYMS
4.1 ABO Blood groups A, B, O and AB
4.2 WBC white blood cell
4.3 RBC red blood cell
4.4 IV intravenous
4.5 mL milliliter
4.6 min minute
4.7 AC anticoagulant
4.8 HES Hydroxyethyl Starch
4.9 BMT Bone Marrow Transplant
4.10 G-CSF Granulocyte colony stimulating factor
4.11 SQ subcutaneous
4.12 PMN polymorphonuclear
4.13 ACD acid citrate dextrose
4.14 CBC complete blood count

5 MATERIALS
5.1 0.9% sodium chloride injection USP
5.2 The following anticoagulant solutions:
   5.2.1 Solution of HE
   5.2.2 46.7% trisodium citrate
5.3 If using peripheral access:
   5.3.1 Needle for the return site that is of sufficient gauge to accommodate the procedure flow rate
   5.3.2 Supplies for preparing the venipuncture site
   5.3.3 Blood pressure cuff
5.4 If using a vascular access device:
   5.4.1 Supplies to disinfect, aspirate from, and connect to the device, according to your standard operating procedures
5.5 Optional supplies:
   5.5.1 Supplies for collecting blood samples
   5.5.2 Apheresis procedure record
   5.5.3 Plasma bag for plasma collection

6 EQUIPMENT
6.1 Spectra Optia Apheresis System
6.2 Spectra Optia IDL Set
6.3 Spectra Optia IDL filler

7 SAFETY
7.1 Follow all safety related standard operating procedures and wear Personal Protective Equipment when handling potentially hazardous blood and body fluids. PPE includes but is not limited to gloves, scrubs, surgical mask, face shield or goggles. Hand hygiene will be performed before and after donor contact.

8 PROCEDURE
8.1 Preparing an Anticoagulant Solution Using HES
   8.1.1 To prepare the correct solution, add 30 mL of 46.7% trisodium citrate solution to 500mL of HES.
8.2 Priming of Donors
   8.2.1 Donors may be stimulated prior to donation with SQ G-CSF to increase the number of circulating granulocytes. The BMT physician will order the cytokine or medication to be used for priming the donor. Priming
cytokine ordered for donors will be administered by a BMT nurse, home health nurse or the donor or family member will be trained in SQ injection.

8.2.2 To further enhance the harvest of granulocytes from the donor, (6% Hydroxyethyl Starch will be infused during the collection. 6% Hydroxyethyl Starch enhances the separation of RBCs (causing a rouleaux effect) which increases the harvest of granulocytes. It is metabolized by the body slowly and is also a volume expander. Potential donors should be questioned about a history of headaches, heart disease, and hypertension. A pregnant donor must be deferred from donation.

8.2.3 Donor screening: refer to APBMT-COMM-001 Donor Selection, Evaluation and Management procedure.

8.3 Selecting the Procedure

8.3.1 Touch Select Procedure. The procedure selection screen appears.

8.3.2 Touch Granulocyte (PMN) Collection.

8.3.3 Touch Confirm. The system loads the procedure software.

8.4 Loading and Priming the Tubing Set

8.4.1 Follow the instructions in the Spectra Optia® Apheresis System Essentials Guide and on the screens to load, test, and prime the tubing set.

8.4.2 If you are using an IDL. Set with the catalog number 10300 and intend to collect plasma during the procedure, you must connect a plasma bag to the replace line between the frangible connector and the cassette before you start the procedure.

8.5 Entering patient data

8.5.1 Touch the buttons on the screen to enter the following patient information:

8.5.1.1 Sex

8.5.1.2 Height

8.5.1.3 Weight

8.5.1.4 Hematocrit (Hct)

**NOTE:** The Spectra Optia system uses sex, height and weight to calculate the patient’s total blood volume (TBV). To change the TBV, touch TBV and enter a different volume.

8.5.1.5 Touch Confirm. The run values screen appears.

8.6 Reviewing and confirming run values

8.6.1 Review the run values that appear on the screen and confirm that they are correct. A black frame appears around the button of the primary run target. To change a value, perform the following steps:
8.6.1.1 Touch the button on the screen that corresponds to the value you want to change. The data entry pad appears.

8.6.1.2 Enter a new value.

**NOTE:** If you change a value, the color of the value on the button changes from white to yellow. Values that were affected by a change appear with a yellow arrow. The arrow points up or down to indicate an increase or decrease in the value as a result of the change.

**NOTE:** You may change the collect pump flow rate to 3mL/min in order to have collect volume of appropriately 300 mLs at end of procedure.

8.6.1.3 When you are finished reviewing the run values, touch **Confirm**.

8.7 Emptying the Saline Drip Chamber

8.7.1 Follow the instructions on the screen to perform the following steps:

8.7.1.1 Empty the saline drip chamber.

8.7.1.2 Rehang the saline container.

8.7.2 Touch Confirm.

8.8 Priming the Inlet Line and the Return Line

**NOTE:** Be sure to perform the steps in the order indicated below and on the screen.

8.8.1 Prime the inlet line. If you are using the diversion bag to collect a blood sample, prime the inlet line to the inlet line manifold only. If you prime the line to the needle, you will dilute the sample with saline.

8.8.2 Prime the return line.

8.8.3 Clamp the inlet line and the return line.

8.8.4 Close the inlet saline line.

8.8.5 If you are not using the diversion bag, clamp and seal the line to the bag, and then remove the bag.

8.8.6 Touch Confirm.

8.9 Connecting the Patient and Starting the Run

**NOTE:** Follow the instructions on the screen to perform the following steps:

8.9.1 Connect the patient lines. If you are performing a peripheral venipuncture, perform the following steps to use the needle protector on the inlet needle

8.9.1.1 Prepare the venipuncture site, according to your standard operating procedure.

8.9.1.2 Position the needle protector away from the wings of the needle so it does not interfere with the venipuncture.
8.9.2 Grasp the wings, remove the tip protector from the needle, and perform the venipuncture.
8.9.3 Secure the needle tubing, according to your standard operating procedure.
8.9.4 Unclamp the inlet line.

8.10 If you are performing a peripheral venipuncture and want to use the diversion bag on the inlet line, perform the following steps before you proceed to Step 8.11:
8.10.1 Perform the venipuncture with the inlet needle.
8.10.2 Unclamp the inlet line.
8.10.3 Unclamp the line to the diversion bag.
8.10.4 Allow the desired volume of blood to flow into the diversion bag.
8.10.5 Clamp and then seal the line to the diversion bag. You may also remove the bag.

8.11 Touch Start Run. The system diverts the saline used to prime the tubing set to the saline container.
8.11.1 Follow the instructions on the screen to close the return saline line.
8.11.2 Touch Continue.
8.11.3 Follow the instruction on the screen to unclamp the return line.
8.11.4 Touch Continue.
8.11.5 Follow the instructions on the screen to empty the saline drip chamber and rehang the saline container.
8.11.6 Touch Continue. The system begins drawing the patient’s blood into the tubing set, and the main run screen appears.

8.12 Adding Anticoagulant to the Collection Bag
8.12.1 Clamp the line above the tubing containing the frangible connector on the accessory line of the collection bag.
8.12.2 Completely break the frangible connector by bending the tubing back and forth.
8.12.3 Using aseptic technique, remove the cap from the luer connector below the sterile barrier filter, and attach a syringe containing the desired amount of anticoagulant to the connector.
8.12.4 Unclamp the line above the frangible connector.
8.12.5 Slowly inject the anticoagulant through the sterile barrier filter into the collection bag.
8.12.6 Clamp the line above the frangible connector.
8.12.7 Remove the syringe from the luer connector.
8.12.8 To ensure that you delivered all of the anticoagulant in the syringe into the collection bag, perform the following steps:

8.12.8.1 Attach a syringe containing at least 2.3mL of saline to the luer connector. (The volume of the accessory line and sterile barrier filter is approximately 2.3mL.)

8.12.8.2 Unclamp the line above the frangible connector.

8.12.8.3 Slowly inject the saline through the sterile barrier filter to flush the anticoagulant in the filter into the collection bag.

8.12.8.4 Clamp the line above the frangible connector.

8.12.8.5 Remove the syringe from the luer connector.

8.13 Using the Sample Bulbs to Obtain a Product Sample

8.13.1 Ensure that the line between the collection bag and the manifold on the sample bulb assembly is clamped.

8.13.2 Clamp one of the lines between the manifold and the sample bulb.

8.13.3 Gently mix the product in the bag to ensure that you obtain a representative sample.

8.13.4 Unclamp the line between the collection bag and the manifold on the sample bulb assembly.

8.13.5 Gently squeeze the sample bulb attached to the line that is not clamped to withdraw the desired amount of the sample.

8.13.6 To express any excess sample back into the collection bag, perform the following steps:

8.13.6.1 Invert the sample bulb, and hold it above the fluid level of the collection bag.

8.13.6.2 Gently squeeze the sample bulb to express the excess sample into the bag.

8.13.7 To use the residual air in the sample bulb to clear the fluid from the line between the collection bag and the sample bulb, perform the following steps:

8.13.7.1 Hold the sample bulb upright and below the collection bag.

8.13.7.2 Gently squeeze the sample bulb. The residual air in the bulb pushes the product from the line into the collection bag.

8.13.7.3 While maintaining pressure on the sample bulb, clamp the line between the manifold and the sample bulb.

8.13.8 Before you remove the sample bulb containing the product sample, permanently seal the line between the clamp below the manifold and the sample bulb.

8.13.9 Disconnect the sample bulb at the seal on the line.

8.14 Removing a Product Sample from the Sample Bulb
8.14.1 Select one of the following three options to remove a sample from the sample bulb:

8.14.1.1 Option 1: Convert the sample bulb to a test tube to remove the sample. To convert the sample bulb to a test tube to remove the sample, cut off the top of the sample bulb at the dotted line on the bulb. The bulb accommodates stoppers suitable for use with 12mm x 75mm test tubes.

8.14.1.2 Option 2: Pour the product sample into a test tube or other container. To pour the sample into a test tube or other container, cut the line below the seal, and gently squeeze the sample bulb to express the sample into the container.

8.14.1.3 Option 3: Aspirate the sample from the sample bulb using a needle or needleless adapter with an attached syringe. To aspirate the sample from the bulb, perform the following steps:

8.14.1.3.1 Insert a needle or a needleless adapter with an attached syringe into the sampling port.

8.14.1.3.2 Invert the sample bulb.

8.14.1.3.3 Slowly aspirate the product sample into the syringe. A small amount of product may remain in the sampling port.

8.14.1.3.4 Remove the needle or the needleless adapter from the sampling port.

8.14.1.3.5 Transfer the sample to a test tube or other container.

8.14.1.3.6 Discard the sample bulb.

8.15 Monitoring the Run

8.15.1 View the information about the run that appears on the main run screen. If you want to return to the main run screen after viewing a different screen, touch the go back button, the active menu button, or the tab for the current screen.

8.15.2 To access additional screens, touch the Run menu button on the main run screen and then touch the tab for the screen you want to access.

8.15.3 Managing Citrate Toxicity

8.15.3.1 Touch the pause button to pause the pumps. An alarm occurs, indicating the procedure was paused and the pumps were stopped.

8.15.3.2 Notify the attending physician of the patient’s condition, according to standard operating procedures.

8.15.3.3 Touch the go back button to go to the main run screen, and decrease the AC infusion rate to the desired value.
8.15.3.4 Touch the active alarm button to return to the alarm screen, and touch Continue to resume the procedure.

8.15.3.5 If decreasing the AC infusion rate does not alleviate the symptoms, touch the pause button to pause the pumps again, and notify the attending physician.

8.15.4 Changing the Entered Hematocrit

8.15.4.1 Touch the Data menu button. The data tabs appear.

8.15.4.2 Touch the Patient Data tab. The patient data screen appears.

8.15.4.3 Touch Hct and enter the new hematocrit.

8.15.4.4 Touch Confirm to save the change.

8.16 Discontinuing the Run

8.16.1 Touch the End Run menu button.

8.16.2 Do one of the following:

8.16.2.1 To discontinue the run and perform rinseback, touch the Rinseback tab and follow the instructions in Step 8.17, “Ending the Run,” starting with Step 8.17.2.2.

8.16.2.2 To discontinue the run and skip rinseback, touch the Disconnect tab and follow the instructions in Step 8.17, “Ending the Run,” starting with Step 8.17.3.2.

8.17 Ending the Run

8.17.1 Extending the run

8.17.1.1 Touch the button for the run target that you want to increase, and use the data entry pad to enter a new value for the target. The run values screen appears.

8.17.1.2 Review the run values.

8.17.1.3 Touch Confirm. The system will continue the run. When the new target is attained, the run targets screen appears and the system sounds a tone.

8.17.2 Ending the run with rinseback

8.17.2.1 Touch Rinseback. The screen appears instructing you to confirm your selection to perform rinseback.

8.17.2.2 Touch Proceed to Rinseback, and then touch Confirm.

8.17.2.3 Follow the instructions on the screen to clamp the inlet line.

8.17.2.4 Touch Continue. The system tests the pressure in the inlet line.
8.17.2.5 Follow the instructions on the screen to open the inlet saline line, and to clamp and then seal the line to the collection bag.

8.17.2.6 Touch Continue. The screen appears that shows the status of the rinseback.

8.17.2.7 When rinseback is complete, follow the instructions in 8.18, “Completing the Procedure.”

8.17.3 Ending the run without rinseback

8.17.3.1 Touch the End Run menu button.

8.17.3.2 Touch the Disconnect tab. The screen appears asking you to confirm your selection to disconnect the patient.

8.17.3.3 Touch Proceed to Disconnect, and then touch Confirm.

8.17.3.4 Follow the instructions in 8.18 “Completing the Procedure.”

8.18 Completing the Procedure

8.18.1 Disconnecting the patient - Follow the instructions on the screen to perform the following steps:

8.18.1.1 Close the inlet saline line.

8.18.1.2 Clamp the inlet line and the return line.

8.18.1.3 Disconnect the patient lines. If you performed a peripheral venipuncture, perform the following steps to remove the needle with the needle protector:

8.18.1.3.1 Release the needle tubing, according to your standard operating procedure.

8.18.1.3.2 Prepare the dressing and place it over the venipuncture site, according to your standard operating procedure.

8.18.1.3.3 Ensure the finger hook on the needle protector points up. Slide the needle protector forward into position under the wings of the needle.

8.18.1.3.4 Place the index finger of one hand inside the finger hook. While maintaining appropriate pressure on the venipuncture site, pull the tubing with the other hand so that the needle slides into the needle protector.

8.18.1.3.5 Dispose of the needle, according to your standard operating procedure.

8.18.1.4 Seal the AC line, the saline line, and the lines to the bags.
8.18.1.5 Touch Unload. The system confirms that the saline lines are closed, and the inlet and return lines are clamped. Then it raises the cassette. The procedure summary screen appears.

8.18.2 Reviewing the procedure summary data
8.18.2.1 Review the data on page 1 of the procedure summary.
8.18.2.2 Touch Next Page.
8.18.2.3 Review the data on page 2 of the procedure summary.

8.19 Removing the Tubing Set
8.19.1 Follow the instructions in the Spectra Optia® Apheresis System Essentials Guide to remove the tubing set.

8.20 Documentation
8.20.1 Record pre and post vital signs on the Run sheet in the spaces provided.
8.20.2 Notify attending physicians of any untoward side effects or abnormal findings.
8.20.3 Record final Run values and end time on the Run sheet in the spaces provided.
8.20.4 Record final fluid balance on the Run sheet in the spaces provided.
8.20.5 Document if Room Temp/Humidity were acceptable during run on PBMT-COLL-016 FRM1 Optia Leukapheresis Run Sheet

8.21 Cleaning of Machine
8.21.1 If a blood spill occurs, inspect the system surface, front panel and centrifuge chamber.
8.21.2 Clean the blood with the Duke Hospital approved disinfecting wipe.
8.21.3 Before and after each use clean the system surface and front panel with the Duke Hospital approved disinfecting wipe.
8.21.4 Document cleaning on PBMT-COLL-016 FRM1 Optia Leukapheresis Run Sheet and PBMT-EQUIP-001 FRM2 Optia Apheresis Machine Quality Control Record

8.22 Starting a New Procedure
8.22.1 To start a new procedure, touch New Procedure on page 2 of the procedure summary. The system resets so that you can select your next procedure.

9 RELATED DOCUMENTS/FORMS
9.1 PBMT-COLL-015 Monitoring Temperature and Humidity
9.2 PBMT-COLL-015 FRM1 Temperature and Humidity Log
9.3 PBMT-COLL-016 FRM1 Optia Leukapheresis Run Sheet
9.4 PBMT-EQUIP-001 FRM2 Optia Apheresis Machine Quality Control Record

10 REFERENCES
10.1 Spectra Optia® Apheresis System Operator’s Manual

11 REVISION HISTORY

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