

## ATTACHMENT 3

### RE: IMPORTANT PRODUCT SAFETY INFORMATION

Pall Medical has received several reports of the **Leukotrap® SC RC Leukocyte Reduction Filtration System for Red Blood Cells With BPF4™ High Efficiency Filter, 16 Segment Tubing, Storage Bag and Sample Pouch (Product code 430-41)** that reveal hemolysis in the attached segment tubing and the storage bags at varying times following filtration. In addition to product code 430-41, this product safety information could also apply to product codes 430-00, 430-45, 430-50 and BPFB.

We are investigating these occurrences to determine the cause of the hemolysis from time of collection to use and to assure proper usage of this product. Significant hemolysis could affect the safety and/or the effectiveness of the transfusion.

Therefore, Pall Medical is providing you with the following **important safety information & recommendations**:

- Review your current inventory of filtered (leukocyte reduced) Whole Blood and Red Blood Cells. Examine the storage bags and attached segments for any evidence of hemolysis. If hemolysis is found, **do not distribute or use the product**; please call and report the information as requested below.
- For units that you are currently processing, and until further notice,
  - Carefully read and follow the instructions for use.
  - Perform filtration as early as possible following collection.
  - Carefully examine all storage bags and attached segments following filtration and immediately prior to distribution. Follow-up as described above.
- We recommend you contact your hospital consignees to encourage them to check their inventory of filtered Whole Blood and Red Blood Cells for hemolysis and to be vigilant in their routine examination of product immediately prior to release for transfusion. If hemolysis is found, **do not use the product**; please have the consignee contact you and report the information requested below. Please verify processing through one of the above product codes.
- To report hemolysis, please immediately call Pall Medical at 1-888-720-8064 with the following:
  - Your Facility Name
  - Contact Name and Title
  - Contact Phone Number (office, fax, mobile and/or pager)
  - BPF4 Product Reorder Code(s) Used (430-00, 430-41, 430-45, 430-50, BPFB)
  - For each lot inspected or processed, provide the lot number. (How much of this lot is unused?)
  - Specify where hemolysis was seen (segment, bag, or both) & color.  
If hemolysis is quantified, specify the method (color chart or assay) and the level
  - Frequency (# units hemolyzed/# units inspected or processed)
  - Age of product at time of filtration
  - From the original product container: the manufacturer and the anticoagulant/additive solution

Pall Medical believes the above steps will be of benefit by providing helpful information. We remain fully committed to investigating these reports and to providing you important information. In addition to our 24-hour hotline, should questions arise, please do not hesitate to contact me directly at 1-516-801-9599.

Yours truly,

Robert A. Dickstein, Ph.D.  
Pall Medical  
Senior Vice President  
Global Regulatory Affairs, Quality Assurance & Scien