

December 17, 2004

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CONTACT NAME  
TITLE  
HOSPITAL OR BLOOD CENTER  
ADDRESS  
CITY, ST ZIP

**URGENT MEDICAL DEVICE RECALL**  
**Leukotrap® SC RC Leukocyte Reduction Filtration System for Red Blood Cells**  
**BPF4™ High Efficiency Filter**  
**Product Codes 430-41, 430-50 and BPFB**

Pall Medical is initiating a limited voluntary recall and we are working closely with the Food and Drug Administration on this action. This action has been initiated due to reports of **hemolysis in the attached segment tubing and the storage bags** observed at varying times following filtration. Pall Medical is recalling only those lots of Leukotrap® SC RC systems where our customers have experienced hemolysis in greater than 5% of the number of leukocyte reduced units produced for each lot consumed at a given blood processing center.

This recall does not extend to any leukocyte reduced blood products produced using the listed lots of our Leukotrap® SC RC system. All leukocyte reduced blood products may remain in use.

- Standard industry practice of examining each unit for hemolysis prior to distribution or use up to its expiry should be followed.
- If low levels of hemolysis are noted, the decision to use or distribute the unit should be guided by internal SOP and the discretion of the Medical Director at each center.
- We recommend you notify your consignees of our December 09, 2004 Product Safety Information letter and the recommendations regarding protocol for blood products in distribution provided therein. A copy of this letter is included as Attachment 3. Also, we recommend that you provide your consignees with a copy of both the December 09, 2004 Product Safety Information Letter and this recall letter.

**Effective immediately**, Pall Medical has changed the labeled *Instructions for Use* for our Leukotrap® SC RC systems, limiting the use of these systems to collected units that are less than five days old. **Do not leukocyte reduce units greater than five days post collection.** In order to limit hemolysis, Pall Medical's revised instructions for use now state: "*Post collection blood should be leukocyte reduced as soon as practicable (preferably within 3 days); however, leukocyte reduction must be performed within five days of collection.*"

To provide a high level of assurance for quality and safety, your assistance in this voluntary recall is both appreciated and necessary. We are informing all consignees of this action regardless of whether you were shipped one or more of the lots of our Leukotrap® SC RC system listed on **Attachment 1**.

- Immediately examine your inventory of unused Leukotrap® SC RC systems and determine if you have any of the listed lots in stock.**
- If you do, discontinue use and place these listed lots on hold in quarantine.**
- If you have further distributed the listed lots to any other processing centers within your organization, please notify them at once of this recall and instruct them to discontinue use and place the product on hold in quarantine.**



When you have completed the above actions, please complete the Recall Response Form (**Attachment 2**). Send the completed form to Pall Medical by **Fax to (516) 484 – 3672**.

- Once we receive your response form, our Customer Service Department will send you a Returned Goods Authorization to return the unused product.
- The Returned Goods Authorization will provide instructions on how to return the systems.

If you need assistance in completing the form or if you have any technical questions, please call our Customer Service Hotline (800) 645 – 6578. Our Customer Service representatives will help you complete the form or they will transfer you to one of our technical representatives to answer your questions. Further information and reference materials are available on our *BPF4<sup>TM</sup> Filter Investigation Web Page* [http://www.pall.com/medical\\_info.asp](http://www.pall.com/medical_info.asp). If any of your consignees would like to talk with a Pall representative directly, please provide them with our Customer Service Hotline number.

Thank you in advance for your assistance in providing the information above. We are confident that an explanation will be found and the corrective measure recommended or undertaken by Pall Medical. We appreciate your confidence and cooperation as we work together to assure the highest level of safety of your blood supply.

Thank you in advance for your assistance in providing the information above.

Yours truly,

A handwritten signature in cursive script that reads "Robert A. Dickstein".

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

Enclosures (3)