

Q & A

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)

1. What is the scope of the problem?

- A few centers in the US have experienced hemolysis with the Pall Medical BPF4 dockable leukoreduction filter (Reorder Code 430-41). The total number of units impacted at this time are 0.27% of the implicated lots. Hemolysis appears anywhere from 24-72 hours post-filtration. Some of the units impacted were greater than 15 days old pre-filtration, and already displayed some measure of hemolysis.
- Specific lots of dockable filter sets implicated in the majority of the hemolyzed units are available on the Pall Web site at http://www.pall.com/medical_info.asp (Attachment 1)

2. What steps has Pall taken?

- Pall is working closely with FDA and members of the Medical Community to determine the root cause of the hemolysis. The Scientific and Laboratory Services division of Pall Corporation and outside testing laboratories under the direction of Pall Research and Development are conducting ongoing studies of the filter, filtration parameters and physical condition of the units. The studies are designed to elucidate and subsequently eliminate the problem.
- As a precautionary measure, Pall Medical has initiated a limited voluntary recall and is working closely with the Food and Drug Administration on this action. Only those implicated lots of unused Pall BPF4 Filters 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, will be recalled.

3. Does the limited recall impact any other leukocyte reduced blood products?

No. The recall does not extend to any other leukocyte reduced blood products using the listed lots of Pall BPF4 Filters. All leukocyte reduced blood products may remain in use.

4. What is Hemolysis?

Hemolysis is the breakage of the red blood cells (RBCs) membrane, causing the release of the hemoglobin and other internal components into the surrounding fluid. It is visually detected by showing a pink to red tinge in the plasma. Hemolysis may have multiple causes. More information about the problem of hemolyzed leukoreduced red blood cells can be found at the California Blood Bank Society (CBBS) Web site at www.cbbsweb.org/enf/leukoredhemol.html.

5. Are there standards for acceptable levels of hemolysis in stored blood in the U.S.?

Currently the Food & Drug Administration (FDA) has recommendations for acceptable hemolysis in deglycerolized red blood cells and for red cells stored in approved/licensed additive solutions which is 1%. The European guideline for acceptable hemolysis in red cell containing products designated for transfusion is 0.8%. For an average packed red cell preparation with a total Hgb of 20 g/dL and HCT of 50%, 1% hemolysis may represent a plasma free Hgb of 500 mg/dL and .8% of 400 mg/dL.

6. What are the risks to patient safety and public health?

- To date, there are no reported adverse affects to patients.
- Excessive free hemolysis results in relatively high levels of free plasma hemoglobin. These higher levels may adversely impact certain patient groups.

7. What do I do with the recalled unused BPF4 Filtration Systems?

To provide a high level of assurance for quality and safety, your assistance in this voluntary recall is both appreciated and necessary.

- Immediately review your inventory of unused Pall BPF4 Filters 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 or consignees, please notify them at once of this recall and instruct them to check their inventory for hemolysis and be vigilant in examination of product immediately prior to release for transfusion. If hemolysis is found, discontinue use and place the product on hold in quarantine.

When the above actions are complete, please return the **Recall Response Form** which can be accessed at http://www.pall.com/medical_info.asp.

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 BPF4 Filters.
- The Returned Goods Authorization will provide instructions on how to return the product.

8. What steps can I take to minimize the impact on my blood center or hospital facility?

For units being processed, follow instructions for use and perform filtration as early as possible after collection (up to five days, preferably three). Routine blood banking practice includes daily inspection of all units of blood and red cells for discoloration of any sort. This inspection continues through the shelf life of the product. We believe that the small number of quarantined filters will neither influence the blood supply nor deprive your patient of the benefits of leukoreduced blood.

9. Whom do I contact with technical questions?

If you need assistance in completing the form or if you have any technical questions, please call our Customer Service Hotline (800) 645-6578. A Pall Customer Service Representative 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™ Filter Investigation Web Page* 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.

10. Has the BPF4 Filter been definitively proved to be the cause of the hemolysis?

No. A variety of other causes unrelated to the Pall BPF4 Filter system are currently also under investigation. These include but are not restricted to the collection bag, anticoagulant, shipping and processing conditions. It is well recognized that some hemolysis is a consequence of red cell storage. Concentrations of hemoglobin greater than 300 mg/dL are encountered in both leukoreduced and non-leukoreduced units.

11. How long will the investigation continue?

Until all factors have been evaluated, the root cause identified, and any necessary corrective actions are implemented.

12. Is inspection of the segment attached to the blood bag an acceptable practice to monitor for hemolysis in the unit?

No. The environmental conditions in the segments are quite different from those in the unit. Observations should be made on the supernatant fluid in the unit itself. In addition, use of color charts to quantify free hemoglobin concentration are recognized as highly inaccurate. Visual assessment tends to overestimate hemolysis.¹ Photoptical determinations are currently the accepted practice to quantify the extent of hemolysis in highly suspect units, eg. Units that are judged suspect on visual inspection.

13. Are there specific precautions that blood centers/banks need to take in regard to leukoreduced packed red cells?

If the product is not associated with the present field action, no further precautions other than GMP are warranted.

14. Who shall I contact if I suspect hemolysis in blood products?

To report a hemolysis incident, call Pall Medical at 1.888.720.8064. Further information and reference materials are available on our *BPF4™ Filter Investigation Web Page* 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.

15. Will the situation cause delays in the shipment of other products manufactured by Pall?

Voluntary recall will not affect our supply of product to blood centers and hospital blood banks. Pall is maintaining sufficient stock to assure no disruption to blood processing operations

¹ K.A. Janatpour, T.G. Paglieroni, V.L. Crocker, D.J. DuBois, and P.V. Holland, Visual assessment of hemolysis in red blood cell units and segments can be deceptive, *Transfusion*, Vol. 44, No. 7, page 984, July 2004.