



Medical

Pall Medical Device Advisory December 17, 2004

Purpose:

- Create forum to communicate with our customers regarding a limited voluntary recall of Pall BPF4 filters due to reports of hemolysis in segment tubing
- Provide factual background
- Communicate next steps
- Hear concerns and answer questions

Speakers:

- Allan Ross, President
- Jerry Delgiacco, VP Product Engineering
- Barry Wenz, Medical Director



Product

- The BPF4 Filter is one of many blood filtration products Pall Medical provides to blood banks for red cell processing.

Factual Description of Event

- Several US centers experienced hemolysis with the Pall BPF4 dockable leukoreduction filter
- Total numbers of units impacted at this time are approximately approximately 0.27% of the population
- Hemolysis appears anywhere from 24-72 hours post-filtration. Some of the units impacted were already >15 days old prior to filtration and already displayed some measure of hemolysis
- No adverse patient events have been reported

Factual Description of Event

- Working in conjunction with FDA, Pall monitored and sought feedback from customers who received implicated lots
- No additional reports submitted
- Important Safety Information Letter issued to customers providing recommendations for inspecting blood product (12/9)
- Identified lots implicated in the majority of the hemolyzed units
- Product Notice letter issued requesting that centers experiencing 10% hemolysis or greater notify consignees and place 3 specific lots on hold (12/13)

Customer Commitment

- Pall recognizes the inconvenience that the situation has caused our customers, and asks for your cooperation and patience as we continue our investigation of the root cause of the occurrences of hemolysis in these limited lots
- We share a mutual interest in providing a high level of assurance of product quality and safety for all our customers and the patients they serve

Root Cause

- The cause of the hemolysis is still undetermined
- Working closely with FDA
- Pall scientists are conducting extensive testing and we hope to have more news to you in the days ahead.

Recall Trigger

As agreed with FDA:

- By the end of today, initiating a voluntary recall of product which demonstrate 5% or greater hemolysis of the total lot used
- Recall all future implicated lots should they occur, based on the above percentage
- Existing inventory leukoreduced with Pall BPF4 can be used

Effectively Immediately

- Pall is changing labeled IFUs limiting the use of the BPF4 filter systems to blood ≤ 5 days old

Operations/Shipment Status

- Recalled product will be replaced with new inventory
- Voluntary recall will not affect our supply of product to all centers
- Maintaining sufficient stock to assure no disruption to blood center operation



Action Plan

- Pall BPF4 Technical Response Team Assembled
- A multidisciplinary group of 15 members consist of Scientists, Product & Chemical Engineers, Six Sigma Quality Engineers and Pall Medical Director
- Working closely with FDA and members of the Medical Community to determine root cause

Action Plan

- Incorporates customer field visits, in-house and independent reference lab testing of implicated/non implicated lots
- Aggressive battery of tests
- Complete assessment of our manufacturing process from source materials components to final product

Testing Update

- Initial assessment addresses 3 areas of investigation:
 - Physiological factors
 - Chemical factors
 - Mechanical factors
- Working expeditiously to determine root cause and conclude the investigation

Clinical Considerations

- Blood, regardless of leukoreduced status, progressively hemolyzes on storage
- Published data confirm that accumulations of free hemoglobin equal to or greater than 300 mg/dL occurs under normal storage conditions
- Visual inspection as provided for by GMP effectively eliminates units that are beyond this range



Clinical Considerations

- Voluntary recall of the involved filtration product,
- Filtration of units = or < 5 days in storage, and
- Continued visual inspection.

Will provide clinically effective and safe blood product

Summary

- Our goal is to provide a high level of assurance for quality and safety for our customers and patients
- Your patience and assistance is much appreciated
- Committed to address any inconvenience the situation may cause our customers
- Information Resources/Forms available
 - Pall Medical Web site (http://www.pall.com/medical_info.asp)
 - Pall Account Manager and PAS Teams
 - Customer Service Hotline (800.645.6578)
 - Pall Management Team



Process to Monitor Progress

- Will continue to communicate with you on a regular basis as we work to determine the cause and resolve the issue in the days ahead



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Q & A