HAEMONETICS®
THE Blood Management Company

June 21, 2016

URGENT Recall Extension
for Leukotrap RC System with RC2D Filter

Attention: Risk Management Director and Material Management
Please forward this communication to all potential users of the product.

Dear Customer:

Haemonetics Corporation is voluntarily recalling **All Lots** of our Leukotrap RC System with RC2D Filter (Re-Order Numbers 129-62 & 129-63), distributed since April 14, 2016.

Reason for the Recall: We have received further reports of higher than expected residual WBC associated with lot numbers beyond those described in our June 8, 2016 recall notification.

Risk to Health: Use of these lots may result in a higher than expected level of leukocytes in transfused blood.

Action to be Taken by Customer: Blood products that have been processed with these lots should not be re-filtered and should be labeled as non-leukoreduced, unless individual units have been tested and found suitable for such labeling. Continued use of these lots will require customers to verify that each unit labeled as leukoreduced was tested and meets standards for rWBC acceptable to FDA. Customers wishing to return unused product to Haemonetics should contact their local customer service representative at the number below.

Product and Distribution Information: The affected product lots were distributed between April 14, 2016 and June 17, 2016. Investigation into the root cause of this issue is on-going.

We ask that ALL CUSTOMERS complete the attached customer acknowledgement form in its entirety ***whether or not*** you have affected product at your site. Once complete, return the form to Haemonetics following the instructions on the form. Your response is vital to our monitoring of the effectiveness of this recall.

Thank you for your business and continued support. We apologize for any disruption this situation may cause your organization. This action is being performed by Haemonetics with the full knowledge of the U.S. Food & Drug Administration.

If you have any questions about this action please do not hesitate to contact me or send a message to Customer Service at 800-537-2802 or customerservicena@haemonetics.com

Sincerely,

David Olson
Vice President, Quality Assurance & Regulatory Affairs

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RECALL ALERT ACKNOWLEDGEMENT FORM

Please complete this form in its entirety and return to Haemonetics:

- ☐ We do not have any of the following products on hand.
- ☐ I have read and understood the conditions necessary to continue use of the affected products identified in the June 20, 2016 Recall Extension letter.

Affected Product

Re-Order Number	Lot Number
129-62	All lots distributed between April 14, 2016 and June 17, 2016
129-63	All lots distributed between April 14, 2016 and June 17, 2016

Name of person completing this form: _____

Title:_____

Phone Number:_____ Email:_____

Institution Name:_____

Institution Address:_____

City:_____ Country:_____ State:_____

_____ _____

SIGNATURE DATE

PLEASE RETURN BY FAX TO +1-781-356-3558 OR SCAN AND E-MAIL TO CORPORATEREGULATORY@HAEMONETICS.COM