HAEMONETICS®
THE Blood Management Company

December 4, 2015

Urgent Medical Device Safety Alert

For ACP215, MCS+9000, MCS+8150, PCS2 Devices

Attention: Risk Management Director, Material Management, Director Biomedical Engineering
Please forward this communication to all potential users of the products shown.

Dear Customer:

Haemonetics Corporation is sending this notification to increase awareness of the proper cleaning process for the pump rotors on the devices listed in this letter.

Reason for Safety Alert: Haemonetics has become aware of customers using harsh chemicals to clean the pump rotor assembly of the ACP215, MCS+9000, MCS+8150 and PCS2 devices. Improper cleaning may damage the pump rollers leading to device malfunction.

Risk to Health: Damage to pump rollers caused by the use of harsh chemicals may cause the incorrect ratio of anticoagulant (AC) to be mixed with blood or blood components collected from the patient/donor. Using these devices, collected blood may be separated into components and directed into collection containers for conservation, or returned to the donor, or transfused to a patient. Elevated levels of AC could lead to a citrate reaction.

Action to be Taken by Customer: Our records indicate that your facility is using one or more of the devices affected by this notice. Haemonetics is providing additional information to clarify the proper cleaning agents to use on the pump rotors. In the case of a fluid spill, only the following solutions should be used:

Acceptable Cleaning Solutions	
Trade/Common Name	**Active Ingredient**
Coverage Plus NPD®	Quaternary ammonium
Super Sani-Cloth® Wipes	Quaternary ammonium
Med-Chem Pink Germicide	Benzyl ammonium chloride
CaviCide™	Benzyl ammonium chloride
MetriCide™	Glutaraldehyde
Virkon® S	Potassium Peroxymonosulfate

Cleaning solutions such as Sporicidin® and Supergard® containing **phenolic compounds should not be used.** In addition, 10% chlorine solutions and very warm water should not be used as these solutions will damage the pump rotors.

Please ensure that all personnel/users are made aware of this cleaning procedure. Retain the User Manual Addendum attached to this letter. In the event that you distributed these devices to other consignees, we request that you notify those consignees of this Safety Alert.

Product and Distribution Information: This notice applies to all serial numbers of the following devices:

- ACP215 Automated Cell Processor
- MCS+9000 Mobile Platelet Collection System
- MCS+8150 Multicomponent Collection System
- PCS2 Plasma Collection Device

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 action.

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

If you have any questions about this action please call our Technical Support team at 1-800-537-2802. Product support for Plasma customers will be provided by calling 1-800-356-3506.

Sincerely,

[redacted]

Brian Burns
Executive Vice President, Quality Assurance & Regulatory Affairs

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SAFETY ALERT ACKNOWLEDGEMENT FORM
ACP215, MCS+9000, MCS+8150, PCS2

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 understand the cleaning instructions provided in the December 4, 2015 Safety Alert letter.
- ☐ Please have a Technical Service representative contact me.

Affected Product

ACP215 Automated Cell Processor	MCS+9000 Mobile Platelet Collection System
PCS2 Plasma Collection Device	MCS+8150 Multicomponent Collection System

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.