

Urgent Field Safety Notice (FSN)

Latham bowl leak

August 13, 2024

Dear Distributor,

Haemonetics Corporation is conducting a voluntary field action on certain lots of Latham bowls.

Reason for the Field Notice:

Haemonetics has received reports from the field of instances in which there has been a significant leak of blood from the Latham bowl into the MCS+ equipment during the apheresis procedure. The leak results when the bottom of the bowl becomes detached, which then leads to a termination of the procedure and required cleaning and servicing of the equipment before the next use. The objective of this FSN is to inform our customers of this possible occurrence and the options available.

- **Frequency of failures and complaints** - The estimated rate of occurrence is approximately 330 per million.
- **Adverse events** - There have been no reports of adverse events associated with this leak.

Product & Distribution Information:

Item Number	Item Description	Lot Number	Quantity
999F-E	CONC PLT & PLS SET W/FILTER	8124054	48
999F-E	CONC PLT & PLS SET W/FILTER	8224086	32

Should you wish to return any affected lots, please contact your Haemonetics account representative. Please note that due to lead times for production, sterilization, and shipping, it may take up to 3 months to receive a full replacement.

Risk to Health:

If the bowl leak happens, as in the reported complaints, there is no harm to the donor because the equipment can detect the leak immediately and stop the procedure. The maximum blood loss due to the bowl being filled with no return during the procedure is 225 ml based on bowl volume. This is less than a whole blood collection, which averages between 450 ml and 500 ml.

The potential for harm to blood center staff due to exposure to blood borne pathogens is unlikely due to the location of the leak (inside the centrifuge of the equipment), the personal protective equipment the blood center staff utilizes as part of standard blood collection process and environment, and blood donor eligibility criteria.

Actions to be taken by Distributor:

Our records indicate that you have distributed the devices affected by this notice. We therefore ask you to perform the following activities:

1. Inform all your impacted customers of this FSN. For your convenience, we have attached a sample customer letter. If required, translate this letter into local language
2. If required by your local regulations, inform the appropriate authorities.
Note: Haemonetics will inform the appropriate European authorities (including EEA and Turkey).
3. Complete the attached acknowledgement form in its entirety **whether or not** you have distributed affected product. 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.

We apologize for any disruption this situation may cause your organization and we thank you for your business and continued support. Haemonetics is committed to continually improving its products and services, with safety and quality as our top priority. This action is being performed by Haemonetics in full transparency with regulatory authorities. Please contact your Haemonetics representative or customer support if you have any questions.

Sincerely,

Andrea Sette

VP International Regulatory & Government Affairs

QSELA@haemonetics.com

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ACKNOWLEDGEMENT and RECEIPT FORM

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Please complete this form in its entirety and return to Haemonetics within 14 days.

- I have read and understood this FSN.
- I have informed all affected customers of this Field Safety Notice.
- I have informed the competent authorities of this Safety Alert if required by national regulations (not applicable for European countries including EEA and Turkey).

- I do not have any of the affected products, OR
- I have some units of the affected products and will continue distributing them, OR
- I have the following quantities of the affected products and wish to return them to Haemonetics. I understand that if this option is chosen, replacement units might not be immediately available.

Product Reference	Affected Lot Numbers	Quantity to be returned

Name of person completing this form: _____

Title: _____

Phone Number: _____ Email: _____

Institution Name: _____

Institution Address: _____

Institution city: _____

Institution Country: _____

SIGNATURE _____ DATE: _____

PLEASE RETURN BY FAX TO +41 22 594 8558 OR SCAN AND E-MAIL TO QSELA@HAEMONETICS.COM