HAEMONETICS®

Urgent Field Safety Notice

125ml and 225ml Cell Saver Centrifuge Bowls

October 30th, 2019

Dear Distributor:

Haemonetics Corporation is voluntarily issuing a Field Safety Notice (FSN) on a potential issue with the 125ml and 225ml disposable bowl sets used on the Cell Saver® 5/5+ and Cell Saver® Elite®/Elite®+.

Reason for the FSN:

Haemonetics Post-Market Surveillance has indicated a new root cause for one of the equipment's error messages which has not been previously described in the equipment user manual.

Investigations into the root cause have managed to replicate the issue and determined that a small number of the associated disposable bowl sets may have the potential to develop leaks (cracks) in the inner core under the centrifugal forces applied by the device. As a result this can lead to fluid becoming trapped inside the bowl. The equipment identifies this issue and issues an error message to the user which reads as *"Long Empty"*. At present the manual already identifies the necessary steps the user must undertake to clear this message. However these steps are insufficient to clear the error message should cracks have developed in the bowl during use.

This communication is intended to provide the user with the necessary additional steps which must be undertaken should this unlikely event occur.

Risk to Health:

It has been determined that if the user does not undertake the additional steps indicated in this communication and ignores the error code presented by the equipment to mitigate the risk; and then continues to return the blood to the patient this could result in a health risk.

Returned blood under these specific conditions may be at risk of containing haemolysed red blood cells and free haemoglobin. Furthermore should the cracked bowl have led to a leak into the inner core there is a possibility of returning recovered blood which has not been completely washed.

Note: The likelihood of experiencing an inner core leak is low. In no circumstances has fluid been found to exit the bowl into the Cell Saver device.

Action to be taken by Distributor:

Our records indicate that you have distributed one or more of the affected devices indicated in this notice. We therefore ask you to perform the following activities:

1. First complete the acknowledgement form supplied without delay and in its entirety ***whether or Not*** you have distributed affected product. The document is named RCL-100285-IE(AA).b and once it is complete, please return to Haemonetics following the instructions on the form. Your response is vital to our monitoring of the effectiveness of this action and may be shared with Haemonetics compotent authorities.
2. Then communicate with your impacted customers. Haemonetics supply you with an example communication under the document named RCL-100285-IE(AA).c. This communication is

Haemonetics S.A.
Signy Centre
P.O. Box 262
1274 Signy-Centre, Suisse
Tel: +41.22.363.9011
www.haemonetics.com

based on Haemoentics document used to communicating to our direct customers. This form may be Modified according to your local needs and requirements. In particular we ask you to pay attention to updating the:

a. Headers and footers
b. Communication method with require your customers to use i.e. Your return email address, your telephone number and/or your fax number
c. The point of contact name and job title who should receive the communication

3. Lastly and if required by your local regulations, inform the appropriate authorities. Please note that Haemonetics will inform the appropriate European authorities located in the European Union (EEA, EFTA and Turkey).

Product and Distribution Information:

The products impacted by this FSN are the following:

Item Number	Description
00260-00	CS5/5+ FASTPACK, 225ML150U RES
00261-00	CELL SAVER 5/5+ BOWL KIT-125ML
00263-00	CELL SAVER 5/5+ BOWL KIT-225ML
00265-00	CS5/5+ FASTPACK, 125ML150U RES
0260F-00	CS5/5+ FASTPACK,225ML, 20U RES
0265F-00	CS5/5+ FASTPACK, 125ML, 20U RE
CSE-FP-125V	CS ELITE FASTPACK,125ML,150U
CSE-FP-225V	CS ELITE FASTPACK,225ML,150U
CSE-P-125	CS ELITE PROCESSING KIT, 125ML
CSE-P-225	CS ELITE PROCESSING KIT, 225ML

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 regulatory authorities.

If you have any questions about this action please do not hesitate to contact me or send a message to QSELA@haemonetics.com.

Sincerely,

Andrew Sette
VP, Quality Assurance &
Regulatory Affairs, International

Haemonetics S.A.
Signy Centre
P.O. Box 262
1274 Signy-Centre, Suisse
Tel: +41.22.363.9011
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HAEMONETICS®

Urgent Field Safety Notice

DISTRIBUTOR ACKNOWLEDGEMENT FORM

125ml and 225ml Cell Saver Centrifuge Bowls

Please complete this form in its entirety and return to Haemonetics within 7 days.

☐ I will inform all affected customers of this Safety Alert.

☐ If necessary I will inform the competent authorities of this Safety Alert if required by national regulations (not applicable for European countries including EEA and Turkey as this is being conducted by Haemonetics).

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 22 363 9058** OR SCAN AND E-MAIL TO **QSELA@HAEMONETICS.COM**

To be issued on dsitributor header

SAMPLE CUSTOMER LETTER

Urgent Field Safety Notice

125ml and 225ml Cell Saver Centrifuge Bowls

October 30th, 2019

To the attention of: **Materiovigilance correspondent**, Risk Management Director and Material Management

Please forward this communication to all potential users of the products

Dear Customer:

The manufacturer Haemonetics makes continuous efforts to supply users of our products with the highest levels of product quality and reliability. In accordance with this principle, Haemonetics is voluntarily issuing a Field Safety Notice (FSN) on a potential issue with Cell Saver® 5/5+ and Cell Saver® Elite®/Elite®+ 125ml and 225ml bowl sets.

Reason for the FSN:

Haemonetics Post-Market Surveillance has indicated a new root cause for one of the equipment's error messages which has not been previously described in the equipment user manual.

Investigations into the root cause have managed to replicate the issue and determined that a small number of the associated disposable bowl sets may have the potential to develop leaks (cracks) in the inner core under the centrifugal forces applied by the device. As a result this can lead to fluid becoming trapped inside the bowl. The equipment identifies this issue and issues an error message to the user which reads as "Long Empty". At present the manual already identifies the necessary steps the user must undertake to clear this message. However these steps are insufficient to clear the error message should cracks have developed in the bowl during use.

This communication is intended to provide the user with the necessary additional steps which must be undertaken should this unlikely event occur.

Risk to Health:

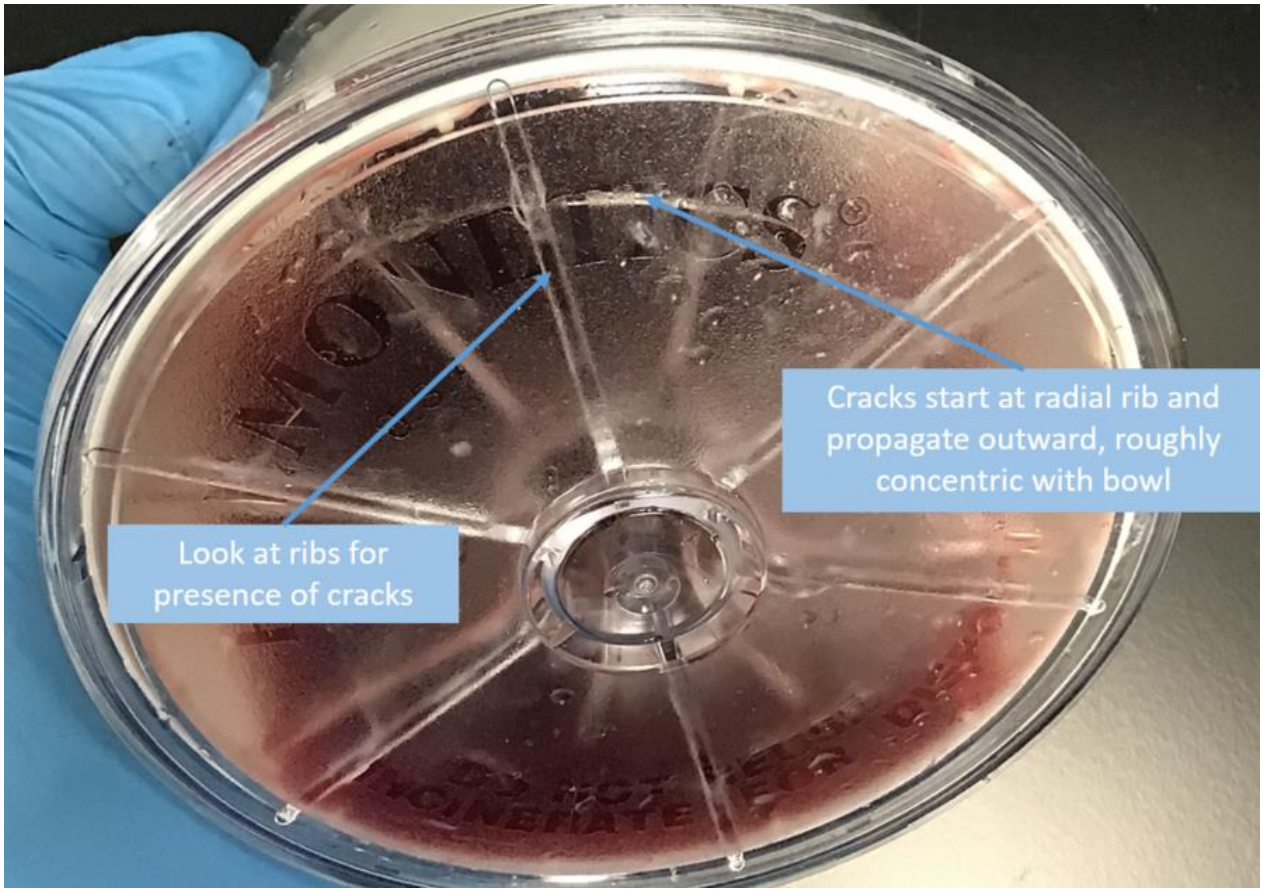
It has been determined that if the user does not undertake the additional steps indicated in this communication and ignores the error code presented by the equipment to mitigate the risk; and then continues to return the blood to the patient this could result in a health risk.

Returned blood under these specific conditions may be at risk of containing haemolysed red blood cells and free haemoglobin. Furthermore should the cracked bowl have led to a leak into the inner core there is a possibility of returning recovered blood which has not been completely washed.

Note: The likelihood of experiencing an inner core leak is low. In no circumstances has fluid been found to leak from the bowl into the Cell Saver device.

Action to be taken by the Customer/User:

1. If an error code indicates "*Long Empty*," complete the current troubleshooting guidance provided in the user manual. These steps will clear the majority of reasons for receiving this error code.
2. If the error message continues, the user should remove the bowl, tilt it upside down and visually check the base for cracks directly on or extending from the ribs. See photo example of where to inspect.



   a. **If no cracks are observed**
   Proceed with using the blood in the reinfusion bag. No further action is required. If continuing with the procedure, use a new processing set.

   b. **If cracks are confirmed in the disposable set bowl**
   The user should assume incomplete washing of the bowl contents. The wash cycle should be repeated on the blood that is in the reinfusion bag.

   Take any residual RBCs in the reinfusion bag and empty the contents into the cardiotomy reservoir to repeat the wash cycle using a new processing set.

   The salvaged blood may be reinfused to the patient.

3. Please retain the disposable and report a product complaint by contacting your local customer service representative or directly to [Insert distributor email address]

4. Please acknowledge you have received this notice by completing the acknowledgement form attached. 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 FSN.

Product and Distribution Information:

The products impacted by this FSN are the following:

Item Number	Description
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CSE-FP-225V	CS ELITE FASTPACK,225ML,150U
CSE-P-125	CS ELITE PROCESSING KIT, 125ML
CSE-P-225	CS ELITE PROCESSING KIT, 225ML

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 regulatory authorities.

If you have any questions about this action please do not hesitate to contact me or send a message to insert distributor email

Sincerely,

Insert distributor contact Name
Insert distributor Job Title

SAMPLE CUSTOMER LETTER

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125ml and 225ml Cell Saver Centrifuge Bowls

ACKNOWLEDGEMENT FORM

Please complete this form in its entirety and return to insert Insert distributor name within 14 days

☐ I acknowledge receipt of this notification.

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 **INSERT DISTRIBUTOR FAX INFORMATION**