

Field Safety Notice

Cell Saver® Elite® disposable processing kits ref. CSE-P-225

July 26, 2016

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

Dear Customer:

Haemonetics S.A. is escalating the Field Safety Notice (FN) issued in April to a product recall on multiple lots of references CSE-P-225 (either sold as stand-alone or included in FastPack, reference CSE-FP-225V).

Reason for the Recall:

For some of the bowls that are used in these sets, the outer diameter at the base of the bowl causes issues with fitting the bowls into the chuck of the centrifuge. If the bowl does not fit into the centrifuge, it cannot be used and the kit needs to be replaced. If the bowl needs to be forced into the centrifuge by the operator, the bowl will still not be properly engaged, causing potential issues with bowl noise, bowls jumping from the centrifuge, and in some cases, broken bowls.

Risk to Health:

If the bowls cannot be fitted into the centrifuge, **there could be a delay in installing the Cell Saver Elite and either a delay in transfusing autologous RBC to a patient or possibly some loss of recuperated blood.** On the other hand, if the bowls are forced into the centrifuge, the bowls can make noises and in some cases break and therefore leak. In these extreme cases, the cell saving procedure needs to be aborted and the salvaged RBC cannot be used. When autologous RBC cannot be used, the backup plan of using allogenic RBC must be triggered by the users.

Action to be Taken by Customer:

- Please discontinue the use of these lots and return any unused product to Haemonetics,
- Complete the attached acknowledgement form (regardless of whether you have any products left) and,
- Return the form within 14 days to Haemonetics following the instructions on the form.

Please contact your local customer service representative (see attached contact list) should you need to coordinate the return and the shipment of the replacement product. Shipment of the

RCL-100217-IE



affected lots was stopped in early April and all lots shipped to you since then and that are not listed in the table below are post-corrective action and 100% inspected for this defect.

Product and Distribution Information:

The products lots impacted by this FSN are the following:

Product ID	Description	Lot #
CSE-P-225	CS ELITE PROCESSING KIT, 225ML	1115013
		1115036
		1115100
		1115101
		1215016
		1215048
		0116030
		0116090
0216064		
CSE-FP-225V	CS ELITE FASTPACK, 225ML	1512018HTT
		1601004HTT
		1601011HTT
		1602010HTT
		1603009HTT

N.B.: This is a comprehensive list and you might not have received all these lots.

Thank you for your business and continued support. We sincerely apologize for any disruption this situation may cause your organization. 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
Senior Director, Quality Assurance &
Regulatory Affairs, EMEA and Distribution

Customer Service Contact List

Region	Contact	Phone
Austria	info.at@haemonetics.com	0800 292 777
Belgium	info.be@haemonetics.com	0800 754 80 (French) 0800 754 82 (Dutch)
Denmark	info.dk@haemonetics.com	8088 7112
France	info.fr@haemonetics.com	0800 90 11 58
Germany	info.de@haemonetics.com	0800 180 88 90
Italy	info.it@haemonetics.com	800 870 200
Ireland	info.uk@haemonetics.com	0808 234 48 17
Luxemburg	info.lu@haemonetics.com	0802 64 90
Netherlands	info.nl@haemonetics.com	0800 0222 707
Norway	info.no@haemonetics.com	020 797 150
Slovenia	distribution@haemonetics.com	N/A
Sweden	info.se@haemonetics.com	020 797 150
Switzerland	info.ch@haemonetics.com	0800 898 898
UK	info.uk@haemonetics.com	0808 234 48 17
United Arab Emirates	distribution@haemonetics.com	N/A



Field Safety Notice
ACKNOWLEDGEMENT FORM

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

- We do not have any of the following products on hand
- We have the following Lots and Quantities in inventory and will dispose of them as instructed in this letter

Name of person completing this form: _____
Title: _____
Phone Number: _____ Email: _____
Institution Name: _____
Institution Address: _____
City: _____ Country: _____

I acknowledge receipt of this Field Safety Notice and understand the instructions provided.

SIGNATURE

DATE

PLEASE RETURN BY FAX TO +41 22 363 9058
OR SCAN AND E-MAIL TO QSELA@HAEMONETICS.COM