HAEMONETICS®

Urgent Field Safety Notice (FSN) – Product Recall

TEG® 5000 - Functional Fibrinogen Reagent (07-034)

February 15, 2023

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

Please forward this communication to all potential users of the products.

Dear Customer,

The purpose of this FSN is to advise you that Haemonetics Corporation is conducting a voluntary product recall related to the TEG 5000 - Functional Fibrinogen Reagent (Item Number 07-034).

Reason for the Field Notice:

During an internal investigation, Haemonetics identified that with specific lots of Functional Fibrinogen kits, the MA and FLEV values (indicating fibrinogen functionality) are low compared to the actual patient condition. The investigation is ongoing to identify and resolve the root cause. There have not been any reported adverse events related to this issue.

Product & Distribution Information:

Below are the associated lots of the affected TEG 5000 Functional Fibrinogen (07-034) product.

Item Number	Item Description	Kit Lot Number	Vial Lot Number	Expiry Date YYYY/MM/DD
07-034	FUNCTIONAL FIBRINOGEN KIT	HMO1131	FF0740	2025/04/30
07-034	FUNCTIONAL FIBRINOGEN KIT	HMO5482	FF0660	2024/07/31
07-034	FUNCTIONAL FIBRINOGEN KIT	HMO5500	FF0660	2024/07/31
07-034	FUNCTIONAL FIBRINOGEN KIT	HMO5568	FF0660	2024/07/31
07-034	FUNCTIONAL FIBRINOGEN KIT	HMO5590	FF0670	2024/08/31
07-034	FUNCTIONAL FIBRINOGEN KIT	HMO5650	FF0670	2024/08/31
07-034	FUNCTIONAL FIBRINOGEN KIT	HMO5651	FF0680	2024/09/30
07-034	FUNCTIONAL FIBRINOGEN KIT	HMO5802	FF0690	2024/12/31

Risk to Health:

The TEG 5000 Functional Fibrinogen test only provides a qualitative estimation of fibrinogen contribution to clot strength. These test results are intended to be used in conjunction with quantitative tests and the patient's clinical presentation along with routine coagulation assessments. The TEG 5000 Functional Fibrinogen test results should not be used in isolation for decision making on when to administer the products aimed at restoring fibrinogen functionality.

In the unlikely situation that a clinician relied solely on these qualitative TEG 5000 Functional Fibrinogen results for decision making on blood product prescription aimed to restore fibrinogen levels, ignoring quantitative fibrinogen tests and other diagnostic tools, the shift in the MA and FLEV values could lead to the administration of therapeutic agents/blood products when the patient does not need them.

The risk to health has been determined to be negligible because the scenario described above is highly unlikely in standard clinical practice and any harm derived from it would be rare to occur.

Actions to be taken by the Customer/User:

Immediately stop using Functional Fibrinogen reagent and identify if you have any inventory of affected lots (see table above). You can find the kit lot number on the product box.

We ask that **all recipients of this notice complete the attached acknowledgement form in its entirety**. Once completed, please return the form to Haemonetics following the instructions on the form. Your response is vital to our monitoring of the effectiveness of this FSN.

- If your form shows that you have unused affected product, Haemonetics Customer Service will contact you and provide instructions for product return.
- We ask that unused vials are kept in their original kits when possible.
- Haemonetics will issue a full refund for returned affected product after it is received.

This recall only pertains to these specific lots of TEG 5000 Functional Fibrinogen (07-034) reagent. The TEG 5000 system, all other reagents and other lots of the Functional Fibrinogen may continue to be used following the user manual and reagent instructions for use.

Haemonetics is continuing its investigation into the product manufacturing defect. 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,

Andrew Sette
VP International Regulatory & Government Affairs
QSELA@haemonetics.com

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ACKNOWLEDGEMENT and RECEIPT FORM
Response Required

TEG® 5000 - Functional Fibrinogen Reagent (07-034)

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

☐ I have read and understand this FSN regarding the product recall of the TEG Hemostasis System Functional Fibrinogen reagent (07-034).

☐ I do not have TEG Hemostasis System Functional Fibrinogen Reagent (07-034) of the affected lots, OR

☐ I have the following quantities of the affected TEG Hemostasis System Functional Fibrinogen Reagent (07-034) lots as listed below:

Product Number	Product Name	Affected Kit Lot Numbers	Affected Vial Lot Number	Quantity of Full Kits in Inventory [Note *0* for no stock]	Quantity of Partially Used Kits in Inventory [Note *0* for no stock]	Of Partially Used Kits, Total Quantity of remaining Vials
07-034	FUNCTIONAL FIBRINOGEN KIT	HMO1131	FF0740			
07-034	FUNCTIONAL FIBRINOGEN KIT	HMO5482	FF0660			
07-034	FUNCTIONAL FIBRINOGEN KIT	HMO5500	FF0660			
07-034	FUNCTIONAL FIBRINOGEN KIT	HMO5568	FF0660			
07-034	FUNCTIONAL FIBRINOGEN KIT	HMO5590	FF0670			
07-034	FUNCTIONAL FIBRINOGEN KIT	HMO5650	FF0670			
07-034	FUNCTIONAL FIBRINOGEN KIT	HMO5651	FF0680			
07-034	FUNCTIONAL FIBRINOGEN KIT	HMO5802	FF0690			

Instructions: Please complete table in its entirety, even if no affected inventory was identified. For example, if you do not have full or partial kit stock of specific affected lots, please input “0” for the appropriate Kit Lots.

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Contact to Facilitate Return [required if you have affected product]:

Name of person to facilitate return: _____

Title: _____

Phone Number: _____ Email: _____

Institution Name: _____

Institution Address: _____

Institution city: _____

Institution Country: _____

Form Completed By [required]:

☐ *Form Completed By* is same as *Contact to Facilitate Return*

Name of person completing this form: _____

Title: _____

Phone Number: _____ Email: _____

Institution Name: _____

Institution Address: _____

Institution city: _____

Institution Country: _____

Signature [required]:

SIGNATURE _____ DATE: _____

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