URGENT – FIELD SAFETY NOTICE

Hemagard Knitted Bifurcated graft

Date:	June 2, 2023
Product Issue:	Textile defect
Affected Product(s):	HGK2010, HGK1608, HGK1609 - Hemagard Knitted graft
Resolution:	Return of the involved product(s)
Affected Serial No(s).:	Please see list on page 3.
Field Action Reference:	RC041
Pages:	4

Dear Customer:

Our records indicate that you bought one or more Hemargard Knitted Bifurcated Vascular Graft with a serial number listed below.

This letter is to inform you of a corrective action that will be performed to prevent a possible hazard to the patients. This corrective action consist in returning all the non implanted products involved to Getinge.

Identification of the issue:

Following an internal non-conformity report, a textile defect was identified within the body of an Hemagard Knitted bifurcated vascular graft, between the two reference lines. The defect in question is a small loop of yarn within the lumen of the graft, which is not visible from the external side of the graft. To be noted, the knitting pattern is correct, and the textile structure of the graft is intact.

Regarding patient safety issue, the presence of a small loop of yarn within the lumen of an HEMAGARD Knitted vascular graft is highly unlikely to have any significant consequences. It is expected that this flaw would go unnoticed by the surgeon, the perioperative staff, or the patient.
In the worst-case scenario, the potential complications arising from this loop of yarn could include thrombosis and subsequent embolism. However, even these complications are highly unlikely to occur. Additionally, in rare cases where a patient with an HEMAGARD Knitted vascular graft underwent an endovascular procedure, there is a slim possibility that the loop could interfere with the progress of the procedure, but this too is unlikely.
It is important to clarify that these complications are highly improbable, considering the small size and low profile of the loop, as well as the high pressure of blood flow in the aorta. In the event that an affected graft was to be implanted in a patient, it would almost certainly have no effect on the outcome of the procedure.

Actions to be taken

1. Please make sure that all caregivers and users of the product(s) listed in the list below are made aware of this Notice.
2. Please make sure that the product(s) listed below are segregated in a secure storage place to prevent any use of these product(s).

Should you have the unused affected product(s), you are eligible for either a replacement or credit.

Affected product(s) should be returned to Getinge per the following process:

- Please complete the Urgent Field Safety Notice Response Form attached to acknowledge that you have received this Field Safety Notice. Please email the completed form to Getinge Office as instructed on the form.
- Pack the product to be returned with the appropriate return documents.

Transmission of this Field Safety Notice:

This Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected devices have been transferred.

Please maintain awareness of this notice and resulting action for the use period of the device to ensure effectiveness of the corrective action.

In cases where you as customer choose not to proceed with completion of the corrective action requirements described above, Getinge cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice.

We deeply regret this inconvenience, but we greatly appreciate your understanding as we take actions to ensure correct product performance.

If you have any further questions or require assistance completing the Customer Response Form, please contact Getinge.

Customer Response Form
RC041

Reference: Urgent Field Safety Notice,
Hemagard Knitted Bifurcated graft

Our records indicate that the device listed below was delivered to your location. Please verify if you have the listed device that is affected and complete the information below.

PRODUCT REF.	SERIAL NO.	LOT NO.	Located at your facility (Yes / No)
HGK2010	1460007138	23D20	
HGK1608	1459429530	23D13	
HGK1608	1459541786	23D20	
HGK1608	1459944990	23D20	
HGK1608	1459950461	23D20	
HGK1609	1459950695	23D20	
HGK2010	1460082044	23D20	
HGK1608	1461034488	23D27	
HGK1608	1461057940	23D27	
HGK1608	1461459389	23D27	
HGK1608	1461462914	23D27	
HGK1608	1461796318	23D27	
HGK1608	1461800713	23D27	
HGK1608	1461818243	23D27	
HGK1608	1461829755	23D27	
HGK1609	1461945849	23D27	
HGK1609	1461950053	23D27	
HGK1609	1461950170	23D27	
HGK1608	1462088386	23D27	
HGK1608	1459109350	23D13	
HGK1608	1459515083	23D13	
HGK2010	1461780560	23D27	

➔ **Complete the last column of above table as appropriate to precise if the affected device is currently located at your facility**

Please check the appropriate boxes below:

☐ We have read the Field Safety Notice and we understand the communication and the required actions.
If checked : please provide information where the affected devices are physically located.

Field Safety Notice Receipt and Customer Response Form Completion and Certification

Current Facility Name			
Contact Name / Title			
Address (no PO boxes, please)			
City, State, Zip			
Phone Number		**Fax:**	

E-Mail Address:	

☐ We have sold/moved the device to another facility.
If checked : please provide new facility information below.

New Facility Name			
Contact Name / Title			
Address*			
City, State, Zip			
Phone Number		**Fax:**	
E-Mail Address:			

Person Responding (please print)	
Title	
Phone Number	
Signature	
Date	

PLEASE RETURN YOUR COMPLETED FORM TO:

XXX XXX
xxxxxxx@getinge.com
Tel: +xxxxxx