URGENT – FIELD SAFETY NOTICE

HEMASHIELD GOLD - Knitted Microvel Double Velour Vascular Graft
HEMASHIELD PLATINUM - Woven Double Velour Vascular graft

Date:	March 23, 2020
Product Issue:	Potential bleeding at the seam line of the branches of Hemashield
Affected Products:	Refer to the below list for your affected products.
Resolution:	Return of all non implanted products of the list.
Affected Serial Nos.:	Refer to the below list for your affected serial numbers.
Field Action Reference:	RC034
Pages:	4

Dear Customer:

Our records indicate that you bought one or more HEMASHIELD GOLD - Knitted Microvel Double Velour Vascular Graft or HEMASHIELD PLATINUM - Woven double velour 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:

The issue was identified through five complaints received between July 2018 and September 2019 reporting intra-operative bleeding at the seam line of the branches of Hemashield grafts.

The investigation was focused on the method used to assemble the branches because the leak was reported at the seamline. This process is performed by operators using different sewing techniques. It was noticed that the products involved in the above mentioned events were prepared by the same operator.

The most likely occurrence, as a consequence of the issue, is a procedural delay due to the necessity to adopt additional hemostatic measures. The delay is expected to be limited and not impacting the flow of the operation and its outcome.
Intraoperative bleeding has been observed when the blood flow has been established through the vascular graft and it was controlled either by compression, clotting agent application or a simple suture. This however, can rarely result in serious or even critical situations especially for patients at greater risk.
Reoperation to control postoperative bleeding is a remote possibility that has not been observed. The presence of mediastinal drainage will help in promptly detect an unusual bleeding. The criticality of this event for the high-risk population derives from the need of a re-operation and the potential impact on the already delicate overall condition.

Based on this medical evaluation, among products listed below, only those which are not implanted need to be recalled.
Explantation of products of the list below is not recommended.

Actions to be taken

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

Should you have the un-used affected product you are eligible for either a replacement or credit.

Affected product 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 Urgent Medical Device Field Safety Notice. Please fax or 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.

When required, the Regulatory Authority of your country has been informed about this communication to customers.

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
RC034

Reference: Urgent Field Safety Notice,
HEMASHIELD GOLD - Knitted Microvel Double Velour Vascular Graft
HEMASHIELD PLATINUM - Woven Double Velour Vascular graft

Our records indicate that the device shown below was delivered to your location. Please verify if you have any of the listed devices that are potentially affected and complete the information below.

PRODUCT REF.	SERIAL NO.	LOT NO.	Located at your facility (Yes / No)
X	111	99	
Y	222	99	

➔ **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:

MAIL
<local SSU address line 1>
<local SSU address line 2>
<local SSU address line 3>
<local SSU address line 4>

CONTACT
<contact address>@getinge.com
Tel: *<SSU contact phone number>*
Fax: *<SSU contact fax number>*