URGENT – FIELD SAFETY NOTICE

Hemashield Platinum Woven graft

Date:	January 24, 2023
Product Issue:	Potentially non sterile product(s) on the market.
Affected Product(s):	M00202175308P0 - Hemashield Platinum Woven grafts
Resolution:	Return of the involved product(s)
Affected Serial No(s).:	1424992146 - lot 22L02
Field Action Reference:	RC040
Pages:	4

Dear Customer:

Following an internal non-conformity report, an underdosing problem with the sterilization process was identified and requires the recall of the affected product.
Indeed, our investigation indicates that you are in the possession of a product identified as above which is potentially non-sterile as it received an underdose of gamma irradiation during the sterilization process. As the sterilization dose was not achieved, the Sterility Assurance Level cannot be guaranteed.

Regarding patient safety issue, underdosing during sterilization is not visible to the naked eye, therefore surgeons and/or operating room staff would not be able to recognize if a prosthetic device has been properly dosed during sterilization. Although it may be extremely unlikely that a patient would be harmed by this, it is possible that the patient may develop a fever in which case an antibiotic and fluids may be effective treatment. When not effective, it may result in an infection and/or sepsis, both of which would be an unlikely occurrence but severe if it should happen.

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
RC040

Reference: Urgent Field Safety Notice,
Hemashield Platinum Woven 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)
M00202175308P0	1424992146	22L02	

➔ **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:

[redacted]