

Field Safety Notice

xx October 2014

Dear Customer

Baxter Healthcare would like to inform you of an issue regarding the following lots of Floseal Hemostatic Matrix (Floleal VH S/D) Product codes 1501510 and 1503353.

Product Code 1501510 Lot numbers beginning with	Product Code 1503353 Lot numbers beginning with
VNY1N005	VNY2P004
VNY1N006	
VNY1N009	
VNY1N013	
VNY1N018	
VNY1N021	

Baxter has received complaints associated with mixing difficulties and high swooshing force (force applied when depressing syringe plunger to homogenize thrombin solution with gelatin matrix). This is mainly reported with first pass of mixing the thrombin with the gelatin. Baxter has reviewed the information provided and conducted a thorough investigation for these complaints. The investigation did not reveal this to be related to a product quality defect, and the medical assessment noted no adverse health consequences to be expected. While no product quality defect was identified, it is understood that due to the compaction of the gelatin matrix within the syringe, the user may experience increased resistance during the mixing process in some cases. Therefore, the following information is provided to you that may be helpful:



Please follow the current guidance to prepare the product.

Before mixing the gelatin matrix with the thrombin solution, we have the following suggestions:

- With the luer cap in place, pull back the gelatin syringe plunger 3-4 millimeters.
- A tap on the gelatin syringe with a surgical instrument such as a mayo scissor will help to

loosen the granules

- Connect the gelatin syringe with the thrombin solution and swoosh as normal to mix.



Baxter apologises for any inconvenience this problem may have caused, and we have implemented corrective measures to reduce the potential for this type of issue in the future. Additionally, Baxter will provide on-site training on mixing techniques and product usage to further assist you. Please contact your local Baxter Representative to schedule an on-site visit from our team.

Please complete the attached Customer Reply Form and return to Baxter by emailing or faxing to the number provided on the form. Returning the Customer Reply Form promptly will prevent you from receiving repeat notices

If you are a distributor, wholesaler or if you provide this product to any other department/facility, please make sure to cascade this information as appropriate.

Additionally, should you have any questions regarding this issue, please feel free to contact me at the number below.

Sincerely,

A handwritten signature in black ink, appearing to read 'I. Gavigan', written over a horizontal line.

Ian Gavigan
Quality Systems Manager
Baxter Healthcare Ltd.
Deansgrange Business Park
Blackrock
Co. Dublin
Ph: 00353 1 206 5500



Customer Reply Form

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Please complete and return one copy of this form by fax to the fax number shown below, or scan and email to the email address shown below, as confirmation that you have received this notification. A fax cover sheet is not required.

Fax : 01 206 5577

Email: QA_Dublin@baxter.com

Facility Name and Address:	
Reply Confirmation Completed By: <i>(Please print name)</i>	
Title: <i>(Please print)</i>	
Telephone Number (including Area Code):	

We have received the above mentioned letter and have disseminated this information to our staff, other services and facilities.

Signature/Date: REQUIRED FIELD	<hr/>
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