

**Urgent Field Safety  
Notice**

19<sup>th</sup> July 2016

**Subject:** UPDATE Field Safety Notice – Device Correction – Cytoluer–Coring of Bags and Particulate Matter Generated – Discontinuation of the product

**Product Name:** Cytoluer

**Product Code:** GMC7405

**Lot numbers:** ALL

Dear Customer,

This communication contains follow up information to the Field Safety Notice (FSN) sent to you on 17<sup>th</sup> November 2015 (Baxter ref FCA-2015-084).

The first FSN communication was related to particulate matter identified inside Viaflo bag when interfaced with the Cytoluer (product code GMC7405). Baxter was making the recommendation to use in-line filtration and was as well reminding standard gowning and gloving practices during administration of cytotoxic solutions. We originally mentioned our intention to incorporate these precautions in the instruction for use of the Cytoluer.

We want, however, to inform you of the business decision to stop marketing the Cytoluer. The product will not be manufactured anymore after September 2016.

The decision was therefore taken not to make any labeling change.

You can continue using the Cytoluer in accordance with the precautions recommended in the original FSN communication as long as the device is available.

We want to inform you as well, that starting on 27<sup>th</sup> May 2016 (lead lot 16E31V115), Baxter started producing the Cytoluer with an optimized needle design to reduce the potential for coring.



Should you have any questions, please contact your Baxter Representative.

Yours Sincerely,

A handwritten signature in black ink, appearing to read 'I. Gavigan', is positioned below the closing text.

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Ian Gavigan  
Head of CQA UK/Ireland  
Baxter Healthcare Ltd.  
Deansgrange Business Park  
Blackrock  
Co. Dublin  
Ph: 01 2065500



**Confirmation of receipt of communication**  
(URGENT FIELD SAFETY NOTICE JULY 2016)

**Cytoluer set**

**Product code: GMC7405**

**All serial numbers from the above product code**

Please complete and return one copy of this form per facility either by fax (**Fax: 01 2065577**) or by **e-mail (qa\_dublin@baxter.com)** as confirmation that you have received this notification. A fax cover sheet is not required.

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

We have received the above-mentioned letter, performed the actions outlined in the letter, and have disseminated the information / documentation to our staff, other services/facilities and customers, as applicable.

<b>Signature/Date:</b>  REQUIRED FIELD	<hr/>
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