

Danish Medicines Agency
Axel Heides Gade 1
2300 København S
Att.: Medicinsk udstyr

22JUL2016

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

This communication contains follow up information to the Field Safety Notice (FSN) sent to you on 19NOV2015 (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.

Customers 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 27th May 2016 (lead lot 16E31V115), Baxter started producing the Cytoluer with an optimized needle design to reduce the potential for coring.

Our records indicate that 1 customer have received this product Denmark. For your information, please find attached the communication that is being sent to this customer.

Should you have any questions, please contact me at aase_bendtsen@baxter.com

Sincerely,
Baxter A/S



Aase Bendtsen
Regulatory Affairs Assistant
T 4816 6423