



Bristol-Myers Squibb Pharmaceuticals Limited

Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH
Tel 01895 523000 Fax 01895 523010

Urgent Field Safety Notice

ViaSpan Solution for Organ Preservation

29 March 2012

Precautionary recall of all batches manufactured since 8th - 9th July 2011

29 March 2012

Attention: Pharmacist / Wholesaler / Transplant Directors and co-ordinators

Details of affected devices:

Batch Number	Expiry Date
16EM0070	14 December 2012
16EG0217	25 July 2012
16EG0074	31 July 2012
16EI0001	01 September 2012
16EK0008	05 October 2012
16FA0001	08 January 2013

Description of the problem:

We wish to inform you that Bristol-Myers Squibb Company (BMS) is now initiating a precautionary recall of all batches manufactured since 8th - 9th July 2011.

On 19th March 2012 BMS was informed of a failure in a routine media fill procedure on the dedicated production line of ViaSpan at Fresenius Kabi Austria, the third party manufacturer of the product. The contaminating organism has been identified as *Bacillus cereus* and has been found during the media fill process (a manufacturing process to check sterility) but not in the Viaspan bags itself.

The last successful media fill was conducted on 8th - 9th July 2011.

Following a review of the investigation to date, Bristol-Myers Squibb is unable to determine at this time if the media fill failure was limited to an event during this procedure. The manufacturer believes the issue is related to a faulty pressure gauge on the filling line that was found to have a small leak. All batches since the last successful media fill have passed all testing, including sterility testing. At the present time, there is no evidence of contamination of the ViaSpan that has been released to the marketplace. However, BMS believes that, on the evidence before it today, it cannot completely assure that batches manufactured since the last successful media fill are free from contamination.

Advise on action to be taken by the user:



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Please immediately quarantine any units of these batches which you have in your possession, if you have not already done so. We will coordinate with Alliance Healthcare any necessary collection of the quarantined product from you and provide a credit.

This recall will result in an out of stock situation. New batches will not be available June 2012 at the earliest.

BMS believes that there are alternative solutions for organ preservation available. However there is guidance provided in the enclosed Dear Health Care Professional letter for those cases where patients recently underwent or will undergo an organ transplantation, in which ViaSpan has or will be used as an organ preservation solution.

Further information on the investigation and on availability of new stock will be provided when available.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact Reference Person:

Medical information

Bristol-Myers Squibb Pharmaceuticals Ltd

Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex, UB8 1DH

tel: 0800 731 1736

e-mail: medical.information@bms.com

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Medical Information at telephone number 0800 731 1736.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Tara Hutton

Director, Global Regulatory Sciences, UK & Ireland



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Urgent Field Safety Notice – Verification Form

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Section A

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name	
Signature	
Date	

Section B

I have read and understood the contents of this Field Action and confirm that our inventory has been checked and we have no inventory of the listed products

Section C

I have read and understood the contents of this Field Action and confirm that our inventory has been checked and the following products have been destroyed

Batch Number	Quantity Returned	Batch Number	Quantity Returned
16EM0070		16EI0001	
16EG0217		16EK0008	
16EG0074		16FA0001	

Please return to: Alliance Healthcare (Distribution) Ltd

Address: 43 Cox Lane, Chessington, KT9 1SN