

URGENT FIELD SAFETY NOTICE – PAS-013-212-FA

**BD Vacutainer® Flashback Blood Collection Needle (21G), Catalogue
Number: 301746**

5th July 2013

Attention: Distributor

This letter contains important information which requires your immediate attention.

Issue Identified:

BD Diagnostics Preanalytical Systems has identified, through customer feedback, that a small number of customers have experienced incidences of blood leakage near the flash chamber when using the BD Vacutainer® Flashback Blood Collection Needle. This blood leakage is attributed to a moulding defect that occurred during the moulding process.

Lot numbers identified as affected:

Lot Number	Expiry Date
2283220	2014-10
2283226	2014-10
2317499	2014-11

The lot number is printed on the device, the shelf pack, and the case carton. Refer to Appendix 1 for guidance on how to locate the lot number.

Advice on Action to be taken by Distributor:

The following actions are required of you:

- Please identify and segregate any product of the affected lot numbers;
- Identify and inform all your customers that have received the affected lot numbers and send them a copy of the attached customer Field Safety Notice (FSN).
- Verify, through whichever means you deem appropriate, that each of these customers receives the FSN, and stops using the affected lots.
- Maintain all records associated with this FSCA
- Return all the affected lot numbers, following the instructions on the Field Safety Notice Acknowledgment & Notice of Return Form. Upon receipt of returned product, BD will send you replacement product at no charge.

NOTE: Even if you do not have any of these affected lots left in your inventory, please complete the attached form indicating you have zero (0) quantity of these affected lots and fax the completed form to: **ADD REGIONAL FAX INFO.**

If you have any questions about the product or the availability of replacement product, please contact your local BD representative or BD office *(insert local telephone number here)*

BD Diagnostics Preanalytical Systems is committed to providing quality products to our customers and we have taken appropriate internal corrective actions. We apologise for the inconvenience this situation may cause.

We confirm that the appropriate regulatory authorities have been informed of these actions.

Yours sincerely,



Lorna Darrock
PAS Regulatory Affairs Manager

Field Safety Notice Acknowledgement & Notice of Return

**BD Vacutainer® Flashback Blood Collection Needle, 21G
Catalogue number 301746**

Please complete the following fields and fax to **ADD FAX INFO**. This will signify your receipt & acknowledgement of the Field Safety Notification. Please complete the form, even if do not have any of the affected lots left in your inventory, entering "0" on the form.

Please include a copy of this notice in any product that is returned.

FAO Returns Team, ref. PAS-013-212-FA

BD
Laagstraat 57,
9140 Temse
Belgium

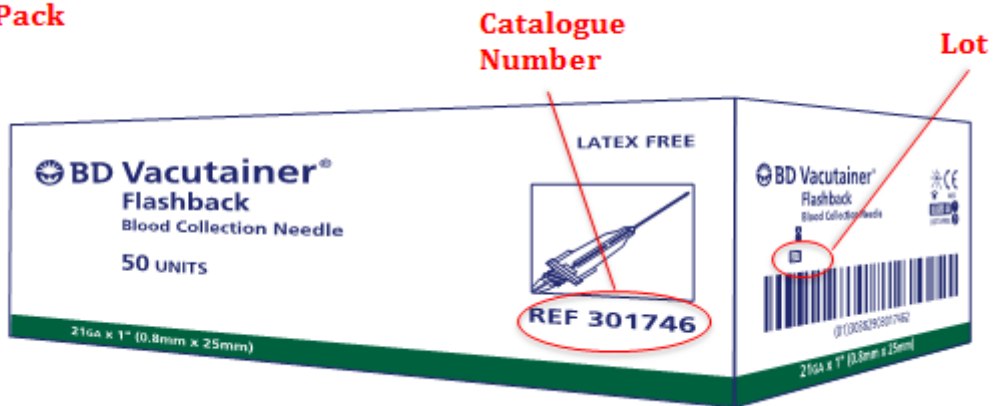
Distributor Name :	
Address :	
Postcode :	City :
Quantity Returned (units):	
Contact Name :	
Job Title :	
Contact Telephone Number:	
Signature :	Date:
Quantity Returned (units) : BD Office use only	

Appendix 1: Location of Lot Number Information

Flashback Blood Collection Needle



Shelf Pack



Case Carton

