The Danby Building Edmund Halley Road Oxford Science Park Oxford OX4 4DQ Tel: 01865 748844 Fax: 01865 717313

www.bd.com



URGENT: Medical Device Field Safety Corrective Action Product Recall

BD Reference: MSS-13-237-FA

Date: 24th June 2013

Subject: BD Plastipak™ 50ml Luer-Lok Syringe – Sterile

Product Code: 300856: NPC: FWC034

Product Recall

BD is recalling syringes that may be potentially affected by a dent/indentation defect on the syringe barrel. This defect could potentially lead to leakage throughout the stopper of the syringe. The recalled product batches can be identified in the table below.

Product Code	Lot Number
300865	1303289
300865	1303294
300865	1303297
300865	1303299
300865	1303300
300865	1303301
300865	1303302
300865	1303303
300865	1304202
300865	1304206
300865	1304211
300865	1304213
300865	1304217
300865	1304219
300865	1304223
300865	1304227
300865	1304228
300865	1304238

NOTE: This notification is different to the 50ml Plastipak™ Luer-Lok Syringes (Product Code 300865) recall that was initiated by BD in April 2013

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

- Please distribute this information to anyone who uses or orders BD Plastipak™ 50ml Luer-Lok Syringes in your institution. Additionally, please ensure that a copy of this letter is provided to any other organisations to which affected devices have been transferred.
- 2. Please check your inventory for BD REF 300865 with the lot numbers identified in the table above and return the product to BD.
- 3. Please complete the Recall Response Card below and return by fax immediately to the number on the Customer Response Card.

Note: THIS FORM MUST BE COMPLETED AND FAXED TO BD MEDICAL.

4. If you have any questions regarding this communication, please contact the following telephone number 01865 781517.

Please accept our apologies for the inconvenience caused by this recall notice. We know that you share in our desire to provide superior quality products and services to both our customers and their patients.

Yours faithfully

Julie Cotterell Marketing Manager

BD Medical - Medical Surgical Systems

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Julia Cosusan



Phone Number

Fax

RECALL RESPONSE CARD for:

Facility Name

BD Plastipak™ 50ml Luer Lock Syringes Reference Numbers: 300865 Please complete by checking the boxes below. We do not have any of the stock of the products listed in the Recall Notice We do have stock of the products listed in the Recall Notice that we will be returning to BD or destroying locally (please provide a destruction certificate to BD if destroying locally) and require replacement products. **REF LOT NUMBER QUANTITY** Please fax to Val Mummery on 01865 781501 or email: val_mummery@europe.bd.com If you have any questions concerning this, please contact BD Customer Care @ 01865 781666 (Option 1) between 9.00am - 5.00 pm, Monday -Friday. Contact Name (please print) Title Signature and Date

Address