

<<Date>>

URGENT: FIELD SAFETY NOTICE – PAS-19-1454

BD Microtainer® Tubes

REF and Lot Numbers: See Appendix 1

Type of Action: Product Removal

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your **immediate** attention.

Dear valued Customer,

BD is conducting a Field Safety Corrective Action to remove specific lots of the BD Microtainer® Tubes due to the potential for damaged tubes. According to our distribution records your organisation may have received the impacted devices.

Description of the Problem

The affected devices are being removed from the market as there is the potential for blood leakage due to a hole or damage at the base of the BD Microtainer® Tube. This defect could result in blood exposure from the leaked sample or potential erroneous results due to an inappropriate blood-to-additive ratio. Patients may need to be re-sampled, which may lead to a delay in treatment.

This product removal is limited to the product codes / lot numbers listed in Appendix 1, no other product codes / lot numbers are affected.

Actions for Customers to take:

1. Please inspect your inventory and locate and quarantine any unused device/s of any of the impacted lot numbers. Destroy all impacted devices or return to your BD local representative / distributor to be destroyed.
2. If you have further distributed the device/s, please identify those users and notify them at once of this product removal.
3. BD recommends discussing the content of this letter with your laboratory director regarding the need to review previous test results associated with these affected lots.

4. Complete the customer response form on page 3 indicating:
 - the quantities destroyed **OR**
 - that your organisation does not have any impacted units left in inventory
5. Return the completed customer response form to <<insert contact details here>> for replacement product or credit **as soon as possible or no later than <<Date>>**.

Contact Reference Person

If you have any questions about this, please contact your local BD representative or the local BD office on <<insert telephone details here>> or e-mail <<insert contact email address here>>.

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

BD is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,

William David
Sr. Director, Quality Compliance,
EMEA Quality Compliance



Customer Response Form - PAS-19-1454

BD Microtainer® Tubes

REF and Lot Numbers: See Appendix 1

Fill out and return this form to BD at fax/e-mail to <<insert fax/email address here>>.

- I confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Tick the appropriate box below

- We do not have any of the affected product as listed in Appendix 1 in our possession.

OR

- We have the following units of the affected product as listed in Appendix 1 in our possession and I confirm that the units have been destroyed / returned (*Please complete the table below with the lot number and the number of units destroyed*)

| Lot Number/s: | Units destroyed / returned (insert quantity below) |
|---------------|---|
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|------------------------------------|--------------------------------|
| Account/Organisation Name: | |
| Department (if applicable): | |
| Address: | |
| Postcode: | City: |
| Contact Name: | |
| Job Title: | |
| Contact Telephone Number: | Contact E-mail Address: |
| Signature: | Date: |

This form must be returned to BD before this action can be considered closed for your account.

Appendix 1

Affected Product Code / Lot Numbers:

| Product Name | Product Code | Lot | Product Name | Product Code | Lot |
|----------------------------|--------------|---------|--|--------------|---------|
| BD Microtainer® Z Tubes | 365964 | 8212774 | BD Microtainer® SST™ Amber Tubes | 365979 | 8180719 |
| BD Microtainer® LH Tubes | 365966 | 821472N | | | 8264509 |
| BD Microtainer® SST™ Tubes | 365968 | 8086508 | | | 8282816 |
| | | 8086517 | 808582N | | |
| | | 8129651 | 808586N | | |
| | | 8173674 | 813766N | | |
| | | 8178701 | 821893N | | |
| | | 8178708 | 827650N | | |
| | | 8220936 | 819351N | | |
| | | 8284578 | 822560N | | |
| BD Microtainer® K2E Tubes | 365975 | 8201643 | BD Microtainer® PST™ LH Amber Tubes | 365988 | 826456N |
| | | 8201645 | | | 827756N |
| | | 8204883 | | | 8213607 |
| | | 8241537 | BD Microtainer® FE Microcollection Tubes | 365993 | 8213615 |
| | | 8253627 | | | |
| | | 8253658 | | | |

Product Code / Lot number Identification:

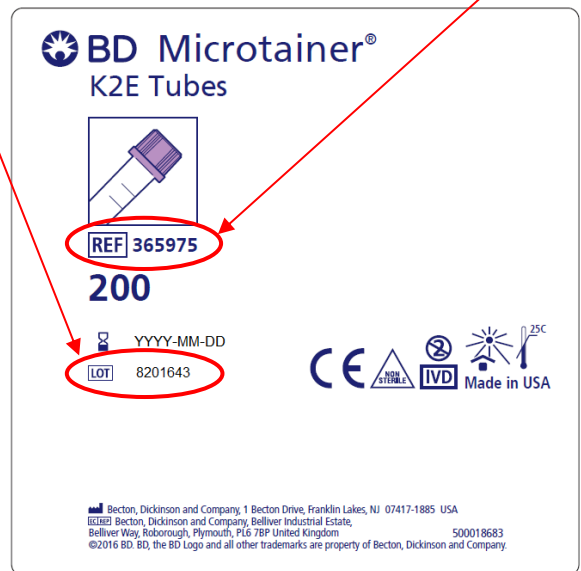
BD Microtainer®
K2E Tubes



Shelf Carton Example

Lot Number

Product Code



Case Carton Example