

6<sup>th</sup> June 2019

**URGENT: FIELD SAFETY NOTICE – PAS-19-1454**

**BD Microtainer<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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 [BDUKFieldAction@bd.com](mailto:BDUKFieldAction@bd.com) for replacement product or credit **as soon as possible or no later than 21<sup>st</sup> June 2019.**

### **Contact Reference Person**

If you have any questions about this, please contact [BDUKFieldAction@bd.com](mailto:BDUKFieldAction@bd.com).

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,

A handwritten signature in blue ink, appearing to read 'William David', written in a cursive style.

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 [BDUKFieldAction@bd.com](mailto:BDUKFieldAction@bd.com).

- 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 / will be returned (*Please complete the table below with the lot number and the number of units destroyed or to be returned*)

Lot Number/s:	Units destroyed / to be returned (delete as applicable) <i>(insert quantity below)</i>

<b>Name of Trust</b>	
<b>Name of Hospital(s) / Facility(s) Covered by this Response</b>	
<b>Hospital / Facility Address</b>	
<b>Email Address</b>	
<b>Telephone Number</b>	
<b>Name</b>	
<b>Signature</b>	
<b>Date</b>	

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

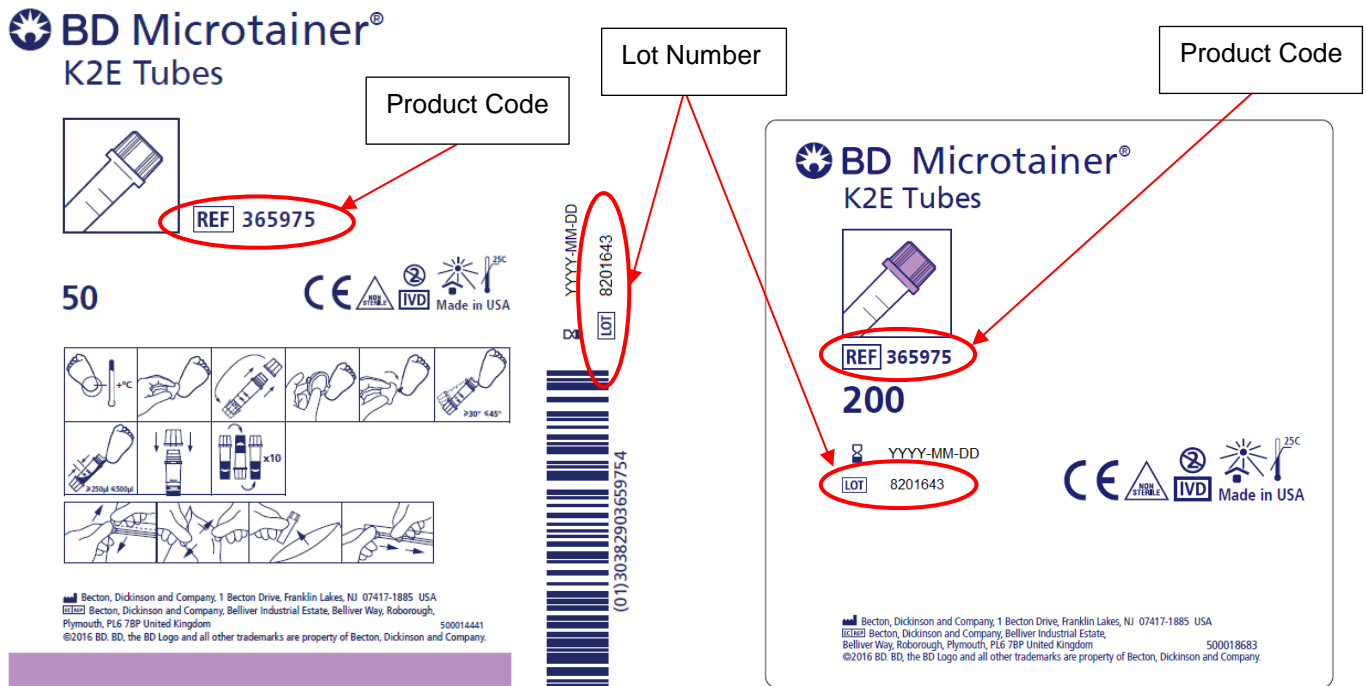
# Appendix 1

## Affected Product Code / Lot Numbers:

Product Name	Product Code	Lot
BD Microtainer® Z Tubes	365964	8212774
BD Microtainer® LH Tubes	365966	821472N
BD Microtainer® SST™ Tubes	365968	8086508
		8086517
		8129651
		8173674
		8178701
		8178708
		8220936
BD Microtainer® K2E Tubes	365975	8201643
		8201645
		8204883
		8241537
		8253627
		8253658

Product Name	Product Code	Lot
BD Microtainer® SST™ Amber Tubes	365979	8180719
		8264509
		8282816
BD Microtainer® PST™ LH Tubes	365986	808582N
		808586N
		813766N
		821893N
		827650N
BD Microtainer® PST™ LH Amber Tubes	365988	819351N
		822560N
		826456N
BD Microtainer® FE Microcollection Tubes	365993	827756N
		8213607
		8213615

## Product Code / Lot number Identification:



The diagram illustrates how to identify the Product Code and Lot Number on two types of packaging for BD Microtainer® K2E Tubes:

- Shelf Carton Example:** The product code is identified as 'REF 365975' and the lot number as '8201643'.
- Case Carton Example:** The product code is identified as 'REF 365975' and the lot number as '8201643'.

Both examples show the 'REF' and 'LOT' fields circled in red, with arrows pointing to labels 'Product Code' and 'Lot Number' respectively. The case carton also shows a 'YYYY-MM-DD' date field.

Shelf Carton Example

Case Carton Example