

<<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)

Account/Organisation Name:	
Department (if applicable):	
Address:	
Postcode:	City:
Contact Name:	
Job Title:	
Contact Telephone Number:	Contact E-mail Address:
Signature:	Date:

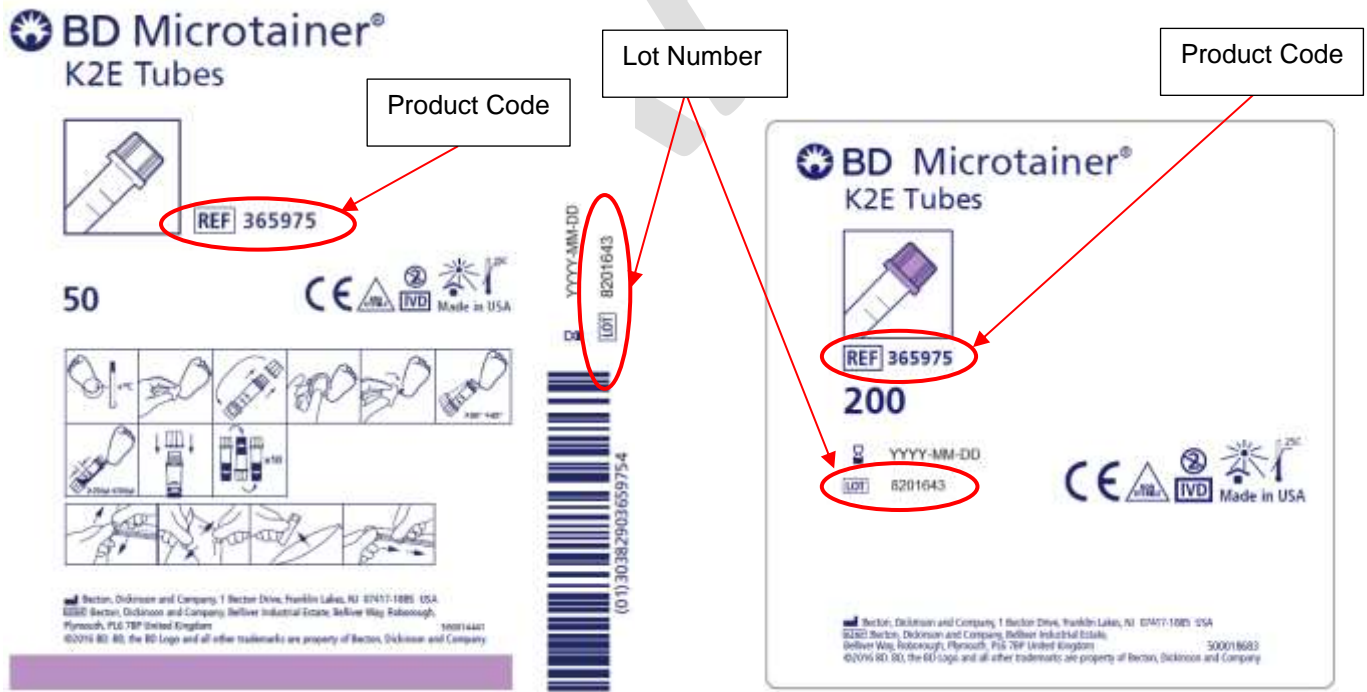
This form must be returned to BD before this action can be considered closed for your account.

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	BD Microtainer® PST™ LH Tubes	365986	808582N
		8129651			808586N
		8173674			813766N
		8178701			821893N
		8178708			827650N
		8220936	BD Microtainer® PST™ LH Amber Tubes	365988	819351N
		8284578			822560N
BD Microtainer® K2E Tubes	365975	8201643			826456N
		8201645	827756N		
		8204883	BD Microtainer® FE Microcollection Tubes	365993	8213607
		8241537			8213615
		8253627			
		8253658			

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:**
 - Product Code:** Located on the front panel, labeled as "REF 365975".
 - Lot Number:** Located on the side of the carton, labeled as "LOT 8201643".
- Case Carton Example:**
 - Product Code:** Located on the front panel, labeled as "REF 365975".
 - Lot Number:** Located on the front panel, labeled as "LOT 8201643".

Shelf Carton Example

Case Carton Example