



11TH of June 2019.

URGENT: FIELD SAFETY NOTICE – PAS-19-1526

BD Microtainer® K2E Tubes

REF: 365975 Lot Numbers: 9017588, 9017590, 9028803 and 9045873

Type of Action: Product Removal

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

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

Dear Distributor,

BD is conducting a Field Safety Corrective Action to remove specific lots of the BD Microtainer® K2E tubes due to insufficient K2E additive. According to our distribution records your organisation may have received the impacted tubes.

Description of the Problem

The impacted BD Microtainer® K2E tubes are being removed as they contain insufficient K₂EDTA additive within the reservoir of the tube due to a manufacturing issue between January 2019 and February 2019. Insufficient additive could result in 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 code / lot numbers listed in Table 1 below. No other product codes or lot numbers are affected. Appendix 1 shows the location of the product code/lot number

Product Code (REF)	Lot Number
365975	9017588
	9017590
	9028803
	9045873

Actions for Customers to take:

1. Please inspect your inventory and locate and quarantine any unused product of any of the impacted lot numbers. Destroy all impacted product or return to your BD local representative / distributor to be destroyed.



BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 Fax:
+41 21 556 30 99
www.BD.com

2. Inform all your customers who have received the affected products mentioned in this letter from your organisation via a Field Safety Notice
 - A template customer Field Safety Notice has been provided for your use which you may adapt and translate as appropriate (Attachment I). BD strongly recommends only adapting the highlighted yellow areas to meet your local needs.
 - Please note, your customers are to communicate directly with you and not with BD.
3. Complete the Distributor Response form on page 3 and return the form to **renata.sakic@bd.com** for replacement product or credit **as soon as possible or no later than the 21st of June**.
4. Maintain all records associated with this Field Safety Corrective Action.
5. BD has informed the relevant authorities of this action where applicable based on BD distribution data. Where applicable and if required, please inform your regulatory agency.

Contact Reference Person

If you have any questions about this, please contact your local BD representative or the local BD office on **+385916062333** or e-mail renata.sakic@bd.com .

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
BD Switzerland Sàrl



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Distributor Response Form - PAS-19-1526

BD Microtainer® K2E Tubes

REF: 365975 **Lot Numbers:** 9017588, 9017590, 9028803 and 9045873

Please read in conjunction with Field Safety Notice PAS-19-1526 and return completed and signed form to as soon as possible or **no later than the 21st of June 2019.** to renata.sakic@bd.com.

We will execute the actions outlined in the Field Safety Notice for affected products in my inventory and/or for affected products that I have distributed to my customers. *(Please complete the table below with the lot number and the number of units destroyed/returned)*

Lot Number/s:	Units destroyed/returned <i>(insert quantity below)</i>
9017588	
9017590	
9028803	
9045873	

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.



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Appendix 1 - Product Code / Lot number Identification

The diagram illustrates the identification of the Product Code (REF) and Lot Number on two types of BD Microtainer K2E Tubes packaging: a Shelf Carton and a Case Carton. Red boxes and arrows highlight the specific information on each.

Shelf Carton Example:

- Product Code (REF):** REF 365975 (circled in red)
- Lot Number:** 8201643 (circled in red)

Case Carton Example:

- Product Code (REF):** REF 365975 (circled in red)
- Lot Number:** 8201643 (circled in red)

Both cartons include the following information:

- BD Microtainer® K2E Tubes
- Quantity: 50 (Shelf) / 200 (Case)
- Storage: 25°C
- CE, IVD, Made in USA
- Barcode: (01)30382903659754
- Manufacturer: Becton, Dickinson and Company

Shelf Carton Example

Case Carton Example