

11TH of June 2019.

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

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
	9017588
365975	9017590
	9028803
	9045873

Actions for Customers to take:

 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.

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- 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.
- 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

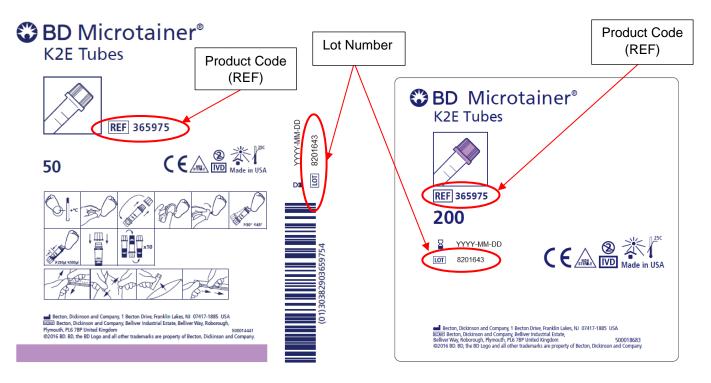
REF : 365975 Lot Numbers : 9017588, 9017590, 9028803 and 9045873				
	•	ety Notice PAS-19-1526 and return an the 21st of June 2019. to renata.s		
and/or for affected		the Field Safety Notice for affected patributed to my customers. (Please of destroyed/returned)	-	
	Lot Number/s:	Units destroyed/returned (insert quantity below)		
	9017588	(
	9017590			
	9028803			
	9045873			
Account/Organisa Department (if ap				
Address:				
Postcode:		City:		
Contact Name:				
Job Title:				
Contact Telephor	ne Number:	Contact E-mail Address:		
Signature:		Date:		
This form	must be returned to RD befo	ore this action can be considered closed fo	r vour account	

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Appendix 1 - Product Code / Lot number Identification



Shelf Carton Example

Case Carton Example

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