30 Tuas ave 2
Singapore 639461
Registration No.: 201114149N

bd.com

URGENT MEDICAL DEVICE RECALL

BD Microtainer® Tubes

04 June, 2019

Dear Customer,

cc: Chairman Medical Board and relevant Head of Departments

Description of the problem and health hazard(s):
BD is conducting a voluntary medical device recall for the catalog and lot numbers listed below for the BD Microtainer® Tubes based on confirmation that there may be damaged tube reservoirs present.

A damaged reservoir may lead to a decreased fill volume causing samples to be insufficient for testing and improper blood-to-additive ratio, potentially producing erroneous results. Recollecting samples and retesting for the patient may be required if a Microtainer® Tube with a damaged reservoir was used. A damaged tube reservoir may result in the potential for blood leakage and exposure to healthcare workers.

The root cause investigation has determined that the damage to the tube reservoirs was caused by an equipment malfunction during the molding process. The equipment malfunction has been corrected. Distribution of the affected lots began on April 11, 2018 and our records indicate you may have received the affected product.

Material	Material Description	Batch
365963	TUBE MICRO W/MICROGARD PLN RD	8268514
365965	TUBE MICRO W/MICROGARD LIHEP GN	815066N
		821471N
		811767N
365967	TUBE MICRO W/MICROGARD SST GLD	8165884
		8170911
		8282848
		8094578
		8094575
365974	TUBE MICRO W/MICROGARD EDTA LAV	8243545
		8288904
		8101701
		8120851
365985	TUBE MICRO W/MICROGARD PST MTGN	827063N
365992	TUBE MICRO W/MICROGARD GLU GR	8268549

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Please Take the Following Actions:

1. Immediately review your inventory for the specific catalog and lot numbers listed below. Destroy all product subject to the recall following your institution's process for destruction.

2. Share this Urgent Medical Device Recall notification with all users of the product to ensure that they are also aware of this recall.

3. Complete the attached Customer Response/Certificate of Destruction Forms and return to your local BD contact whether or not you have any of the impacted material so that BD may acknowledge your receipt of this notification and process your product replacement.

4. Report any adverse health consequences experienced with the use of this product to BD.

Actions Taken by BD:

1. Corrective actions have been initiated to prevent recurrence of the identified root cause.

2. BD will provide replacement product for all unused, discarded inventory.

Contact Information:

Please use the contact your local BD representative for complaints, adverse event reports, or questions regarding this recall.

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

Yours Sincerely,

Grace Liew
Business Manager (Singapore, Malaysia, Brunei)

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CUSTOMER RESPONSE FORM

PAS-19-1454-FA

BD Microtainer® Tubes

Please assist BD by promptly returning this form to your BD contact by 28 June 2019.

Facility: _____

Please use full, current facility name. Do not use initials

Street Address: _____
City: _____
State: _____
Zip: _____

Contact Person: _____
Telephone No.: _____
Fax No.: _____

Email Address:
_____

I have read and understood the attached notice.

Name:
Title:
Signature/Date: