30 Tuas Avenue 2
Singapore 639461
tel: 65 6861 0633
fax: 65 6432 2060
www.bd.com
Registration No. 201114149N

Helping all people live healthy lives

February 2016

URGENT PRODUCT RECALL

Product Name	Cat. Number	Lot Number	Expiry date
BD SurePath™ GYN Preservative Vial Kit 500 ea	490527	5021971	31 January 2018
		5026951	31 January 2018
		5058537	28 February 2018
		5077993	31 March 2018
		5091595	31 March 2018
		5098734	30 April 2018
		5124528	30 April 2018
		5141835	31 May 2018
		5155636	30 June 2018
		5162962	30 June 2018
		5187810	30 June 2018
		5224627	31 August 2018

Dear Customer,

BD has confirmed that a portion of BD SurePath™ collection vials associated with specific production lots may contain caps that are cracked which can lead to leaking of the preservative fluid. Our records indicate that you may have received vials from the affected lots specified listed on the table above.

BD recommends that you check current unused inventory prior to use, identify affected vials and discard per standard lab practices. We will issue replacements for the discarded material. Additionally, please wear suitable protective clothing, gloves, and eye/face protection and follow appropriate biohazard precautions when handling all samples, as leaking caps may increase the risk of chemical or biological exposure. Cytological specimens may contain infectious agents.

If leaking is observed after specimen collection, it is important to verify that adequate volume is available before continuing with the test. Vials from the affected lots should be processed normally if sufficient volume is present as determined through your routine laboratory procedures.

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Immediately review your inventory and determine if you have any of the affected lot. Please discontinue use and return the affected lot from inventory to your distributor for destruction. Upon receipt of the returned product, we will issue product replacement.

2. As a requirement of our Regulatory Tracking Process, we request that you complete the enclosed form, even if you no longer have the affected lot listed in your inventory. Please sign and fax the completed form to your local BD contact confirming that you have read and understood this notice.

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We also request that you forward this notice to any other person or groups within your organization for whom this information may be relevant. Any adverse health consequences experienced with the use of this product should be reported to BD.

For all other inquiries please contact your local BD representative and they will ensure that you are put in contact with the most appropriate individual to address your concerns.

Please accept our apology for any inconvenience this may cause. BD is committed to providing you with the highest quality products. Thank you for your continued support.

Regards,

[redacted]
Rose Kwong
Senior Regulatory Affairs & Compliance Executive

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(CUSTOMER ACKNOWLEDGEMENT)

Please fill in the information below so that we may acknowledge your receipt of this notification. Simply complete and return the completed form to your local distributor contact.

Please tick as appropriate.

- ❑ We do not have any stock of the below affected products on hand.
- ❑ We have a total of _____ unit(s) of the affected product listed below in our inventory to be returned to distributor for destruction.

Note: Please provide details on the quantity of affected units as per below table.

Cat. Number	Lot Numbers	Quantity (eaches) received	Quantity (eaches) used	Remaining Quantity (eaches) in inventory to be returned to distributor for destruction
490527	5021971			
	5026951			
	5058537			
	5077993			
	5091595			
	5098734			
	5124528			
	5141835			
	5155636			
	5162962			
	5187810			
	5224627			

Completed by:

Name: _____ **Signature/Date:** _____

Facility: _____
Please use full, current facility name. Do not use initials.

Street Address: _____

Telephone No.: _____ **Fax No.**: _____

Company stamp: