

May XX, 2020

**URGENT: FIELD SAFETY NOTICE – IDS-20-1985 (Rev 2)**

**BD BBL™ Gram Crystal Violet 250mL, Gram Crystal Violet 3.8L & Gram Stain Kit**

**REF & Lot Numbers:** Refer to Table 1 below

**Type of Action:** Product Removal

**Attention: Clinical Personnel, Risk Managers, Biomedical Personnel**

This letter contains important information which requires your immediate attention.

Dear Customer,

BD is issuing this Field Safety Notice to remove specific lots of BD BBL™ Gram Crystal Violet 250mL, BD BBL™ Gram Crystal Violet 3.8L and BD BBL™ Gram Stain Kit, as listed in Table 1 below. According to our distribution records your organisation may have received these devices which were shipped from BD between December 2019 and March 2020.

REF	Product Description	LOT Number	Date of Manufacture	Expiration Date
212525	BD BBL™ Gram Crystal Violet 250mL	9269800	07-Oct-19	30-Apr-21
		9352484	28-Jan-20	31-Jul-21
		9352492	29-Jan-20	31-Jul-21
212526	BD BBL™ Gram Crystal Violet 3.8L	0027824	17-Feb-20	31-Aug-21
		9296631	25-Nov-19	31-May-21
212539	BD BBL™ Gram Stain Kit	0007261	29-Jan-20	30-Jun-21
		0014322	16-Jan-20	30-Jun-21
		0041114	12-Feb-20	31-Jul-21

Table 1: List of impacted products

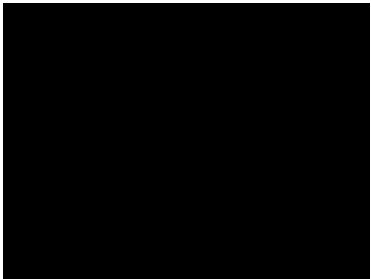
**Description of the Problem**

Through customer feedback, BD has discovered the specific lots of BD BBL™ Gram Crystal Violet 250mL, BD BBL™ Gram Crystal Violet 3.8L and BD BBL™ Gram Stain Kit listed in Table 1 above have the potential to exhibit increased levels of artifacts which could be difficult to distinguish from gram positive cocci.

Use of products with increased levels of artifacts could result in a false-positive Gram stain. Gram stain results must be confirmed with additional procedures, but if these protocols are not followed, a false-positive could lead to administration of unnecessary antibiotics or surgical procedures.

**Advice on actions to be taken by the Distributor:**

1. Inspect your inventory, locate and quarantine any units of the impacted devices listed in Table 1.
2. If you have further distributed the product, please identify those facilities, notify them at once of this product removal and have them return the affected product to your facility.



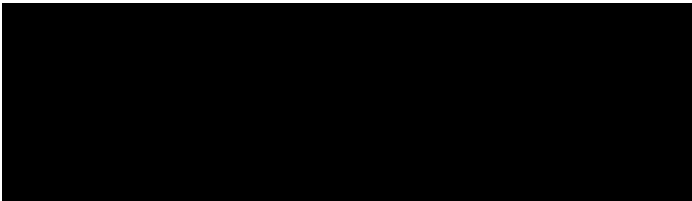
3. Destroy any unused units of the affected product and complete the customer response form on page 3 indicating:
  - o the quantities destroyed **OR**
  - o that your organisation does not have any impacted units left in inventory
  
4. Return the completed Customer Response Form to **<<email address>>** as soon as possible or **no later than May 22<sup>nd</sup>, 2020.**

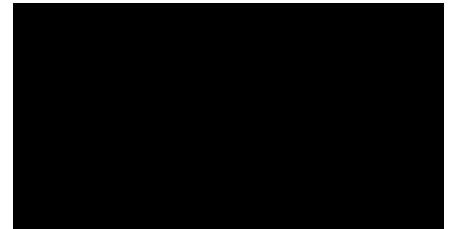
Should you have any questions or require assistance relating to this Field Safety Notice, please contact your Local BD representative at **<<insert contact details>>**.

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 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,





## Customer Response Form – IDS-20-1985 (Rev 2)

### BD BBL™ Gram Crystal Violet 250mL, Gram Crystal Violet 3.8L & Gram Stain Kit

REF & Lot Numbers: Refer to the table below

Please read in conjunction with Field Safety Notice IDS-20-1985 (Rev 2) and return, completed and signed, as soon as possible or **no later than May 22<sup>nd</sup>, 2020** to <<email address>>.

- 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 Table 1 in our possession.

**OR**

We have have units of the affected product as listed in Table 1 in our possession and I confirm that the units have been destroyed (*Please complete the following table with the quantities of units destroyed*)

REF	Product Description	LOT Number	Quantity Destroyed
212525	BD BBL™ Gram Crystal Violet 250mL	9269800	
		9352484	
		9352492	
212526	BD BBL™ Gram Crystal Violet 3.8L	0027824	
		9296631	
212539	BD BBL™ Gram Stain Kit	0007261	
		0014322	
		0041114	

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

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