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8th January 2024

URGENT: FIELD SAFETY NOTICE – IDS-23-4851

BD BBL™ Sensi-Disc™

REF: Refer to Appendix 1 **Lot Numbers:** Refer to https://legacy.bd.com/alerts-notices/IDS-23-4851.asp

Type of Action: Product Removal / Advisory

Attention: Clinical Personnel, Risk Managers, Laboratory Personnel, Purchasing Managers

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

Dear Customer,

BD is conducting a Field Safety Corrective Action for specific lots of **BD BBL™ Sensi-Disc™**. According to our distribution records your organisation may have received the impacted product in Appendix 1. Product was distributed by BD between March 2019 and November 2023. BD has an on-line tool to support the identification of impacted lot numbers located at: **https://legacy.bd.com/alerts-notices/IDS-23-4851.asp**

Description of the problem

BD confirmed through a recent evaluation of BD BBL™ Sensi-Disc™ product that twenty-eight (28) out of thirty (30) antimicrobial discs showed reproducibility, accuracy, and/or Quality Control (QC) failures when tested with *Haemophilus spp.* Testing with other bacterial pathogens (where indicated) is not affected.

Clinical risk

Based on findings from internal and reference lab testing, there is a possibility of reproducibility, accuracy and/or QC failures in antibiotic susceptibility testing (AST) for H. influenzae. Performance is highly variable depending on plate manufacturer, AST guidelines utilised, and the antibiotic tested. This may cause product discard, delayed results, or additional adverse diagnostic outcomes, such as a delay in diagnosis, the selection of inappropriate antibiotics or extended duration of antibiotic exposure and the treatment process.

To date there has been no adverse events worldwide related to this issue.

BD Actions:

- BD is investigating root cause and will implement appropriate corrective and preventative measures to prevent recurrence.
- BD will issue credit to customers that have catalogue number 291270, following receipt of the completed Customer Response Form.

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- Future lots of BD BBL™ Sensi-Disc™ provided (excluding catalogue number 291270) will be labelled with a sticker notifying customers "This product should not be used for the semi-quantitative in vitro susceptibility testing of *Haemophilus influenzae*".

Actions for Clinical Users

- Users should refrain from conducting AST testing for *Haemophilus* species with affected BD BBL™ Sensi-Disc™. The affected product can continue to be used with other bacterial pathogens (where indicated).
- Cease use of catalogue number **291270**, which is solely intended for AST testing for *Haemophilus influenzae*.
- Previous test results do not need to be reviewed and no additional clinical actions are recommended.

NOTE: With the exclusion of catalogue number **291270**, other catalogue numbers with lot numbers in scope of this action **can continue to be used** with other bacterial pathogens (where indicated).

Customer Actions:

For impacted lots of catalogue number **291270 (only):**

- Identify and quarantine all unused affected units of impacted lots of catalogue number **291270**.
- Make a note of the lot numbers, then destroy the affected units of catalogue number **291270**.
- **NOTE:** Other catalogue numbers with lot numbers in scope of this action **can continue to be used** with other bacterial pathogens (where indicated).

For **all** other catalogue numbers in scope of this action:

- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 16th February 2024**.
- Circulate this notice to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred.
- If you experience any issues, please report as a complaint as per your normal process.

Distributor Actions:

For impacted lots of catalogue number **291270 (only):**

- Cease distribution of catalogue number **291270 (only)**.
- Identify, quarantine, making a note of the lot numbers then destroy all affected units of catalogue number **291270 (only).**
- Identify the facilities where you have distributed all affected product and notify them immediately of this notice.
    - Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes by **16th February 2024**.
- Complete and return the Customer Response Form following completion of your reconciliation activities.
- If you experience any issues, please report as a complaint as per your normal process.

For **all** other catalogue numbers in scope of this action:

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- Identify the facilities where you have distributed all affected product and notify them immediately of this notice.
    - Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes by **16th February 2024**.
- Complete and return the Customer Response Form following completion of your reconciliation activities.
- For future shipments of impacted lots from your inventory (**excluding** catalogue number **291270**, which should be discarded), ensure this letter is forwarded for awareness, until your inventory has depleted. No further action is required for lots that are not listed, as these have been labelled with a statement to not use the affected product for *Haemophilus influenza.*
- If you experience any issues, please report as a complaint as per your normal process.

	End User with Inventory	End User with ZERO inventory	Where to send completed form
Purchased **directly** from BD	**Product removal**: Credit will be issued for destroyed affected units of catalogue number **291270** on return of response form **Advisory**: Ensure that all recommended actions have been implemented as required.	**Product removal**: Check the box indicating "no inventory". **Advisory**: Complete form in its entirety and retain a copy of this notification for your records.	BDRegaffairs_GSA@bd.com
Purchased from a **distributor/3rd party**	**Product removal**: Contact your distributor with the response form to arrange credit **Advisory**: Ensure that all recommended actions have been implemented as required.	**Product removal**: Check the box indicating "no inventory". **Advisory**: Complete form in its entirety and retain a copy of this notification for your records.	Return the form to your distributor /3rd party

Contact reference person

If you have any questions about this, please contact your local BD representative or the local BD office on **+972 (54) 6797** or e-mail **omer.perlman@bd.com**.

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 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,

Lorna Darrock
Associate Director, Post Market Quality
EMEA Quality

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Customer Response Form – IDS-23-4851

BD BBL™ Sensi-Disc™

REF: Refer to Appendix 1 **Lot Numbers:** Refer to
https://legacy.bd.com/alerts-notices/IDS-23-4851.asp

Return to BDRegaffairs_GSA@bd.com as soon as possible or **no later than the 16th February 2024.**

- **I confirm this Field Safety Notice has been read, understood and that all recommended actions have been implemented as required.** *(Complete the fields below).*

Account/Organisation Name:	
Department *(if applicable)***:**	
Address:	
Postcode:	**City:**
Contact Name:	
Job Title:	
Contact Telephone Number:	**Contact E-mail Address:**
Name of your supplier for this product *(if not direct from BD)*	
Signature:	**Date:**

For impacted lots of catalogue number 291270 (only):

Tick the appropriate box below

☐ We do not have/have already used affected lots of catalogue number 291270 in our facility. ***(All product that is not available for destruction will be considered as dispositioned at your location and therefore physically unavailable unless otherwise specified.)***

OR

☐ We have the following units of the affected lots of catalogue number 291270 and confirm that the units have been destroyed ***(Please complete the table below with the lot number and the number of units. Credit will only be sent on completion and return of this form.)***

REF:	Lot Number/s:	Units destroyed/returned *(insert quantity below)*
291270		

This form must be returned to BD before this action can be considered closed for your account. If you were forwarded this Field Safety Notice via a distributor/3rd party, please return your completed form to that organisation for reconciliation purposes.

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Appendix 1 - Product Codes

Refer to **https://legacy.bd.com/alerts-notices/IDS-23-4851.asp** for impacted lot/batch numbers.
This Field Safety Corrective Action is limited to the product codes listed in Appendix 1.

Product Removal:

Catalogue Number (REF)	Description	UDI	Expiration date (up to and including)
291270	Sensi Disc Augmentin - 3µg	(01) 30382902912706	29 July 2028

Advisory:

Catalogue Number (REF)	Description	UDI	Expiration date (up to and including)
231251	Sensi Disc Minocycline – 30 µg	(01) 3 038290 231251 3	29 July 2028
231263	Sensi Disc Ampicillin - 2 µg	(01) 3 038290 231263 6	
231264	Sensi Disc Ampicillin - 10 µg	(01) 3 038290 231264 3	
231274	Sensi Disc Chloramphenicol - 30 µg	(01) 3 038290 231274 2	
231344	Sensi Disc Tetracycline – 30 µg	(01) 3 038290 231344 2	
231539	Sensi Disc Sulfamethoxazole with Trimethoprim 23.75/1.25 µg	(01) 3 038290 231539 2	
231544	Sensi Disc Rifampin – 5 µg	(01) 3 038290 231544 6	
231607	Sensi Disc Cefotaxime – 30 µg	(01) 3 038290 231607 8	
231621	Sensi Disc Cefuroxime – 30 µg	(01) 3 038290 2316214	
231629	Sensi Disc Amoxicillin with Clavulanic Acid – 20/10 µg	(01) 3 038290 231629 0	
231633	Sensi Disc Ceftazidime - 30 µg	(01) 3 038290 231633 7	
231635	Sensi Disc Ceftriaxone - 30 µg	(01) 3 038290 231635 1	
231641	Sensi Disc Aztreonam - 30 µg	(01) 3 038290 231641 2	
231645	Sensi Disc Imipenem – 10 µg	(01) 3 038290 231645 0	
231653	Sensi Disc Cefaclor - 30 µg	(01) 3 038290 231653 5	
231658	Sensi Disc Ciprofloxacin – 5 µg	(01) 30382902316580	
231660	Sensi Disc Ampicillin with Sulbactam – 10/10 µg	(01) 3 038290 231660 3	
231664	Sensi Disc Cefixime - 5 µg	(01) 30382902316641	
231672	Sensi Disc Ofloxacin – 5 µg	(01) 3 038290 231672 6	
231673	Sensi Disc Cefpodoxime – 10 µg	(01) 00382902316732	
231674	Sensi Disc Cefpodoxime – 10 µg	(01) 30382902316740	
231678	Sensi Disc Clarithromycin – 15 µg	(01) 30382902316788	
231682	Sensi Disc Azithromycin -15 µg	(01) 30382902316825	
231692	Sensi Disc Piperacillin/Tazobactam – 100/10 µg	(01) 3 038290 231692 4	
231696	Sensi Disc Cefepime - 30 µg	(01) 3 038290 231696 2	
231704	Sensi Disc Meropenem – 10 µg	(01) 3 038290 231704 4	
231705	Sensi Disc Levofloxacin – 5 µg	(01) 0 038290 231705 0	
231706	Sensi Disc Levofloxacin – 5 µg	(01) 3 038290 231706 8	
231758	Sensi Disc Moxifloxacin – 5 µg	(01) 3 038290 231758 7	
232174	Sensi Disc Ertapenem – 10 µg	(01) 0 038290 232174 3	
232175	Sensi Disc Ertapenem – 10 µg	(01) 3 038290 232175 1	
232219	Sensi Disc Doripenem - 10 µg	(01) 3 038290 232219 2	
232231	Sensi Disc Ceftaroline – 30 µg	(01) 3 038290 232231 4	
291308	Sensi Disc Cefotaxime – 5 µg	(01) 30382902913086	