



**BD**

Fortschritt für die  
Welt der Gesundheit

bd.com

BD · Postfach 10 16 29 · 69006 Heidelberg



September 20th 2018

**URGENT: FIELD SAFETY NOTICE**

Field Safety Corrective Action: **BDDC-18-1331-FAC**  
Date: **September 2018**  
Type of Action: **Voluntary Product Recall**

Dear Distributor

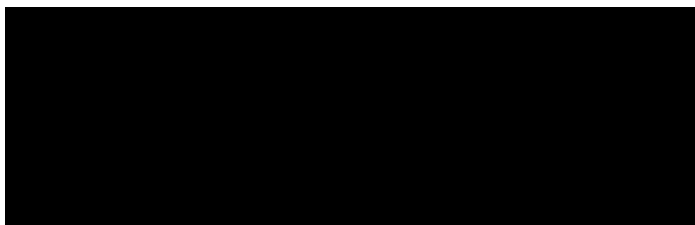
Please find the attached Field Safety Notice (BDDC-18-1331-FAC) concerning BD's BD Micro-Fine Ultra™ 0,25mm (31G) x 5mm (Product code 325104, Lot number 8149886)

We request that you take the following actions in **Actions Required of You** below (page 2) in response to this Notice. We apologise for any inconvenience that this issue causes you.

BD is committed to ensuring that safe and effective product is available to customers and this Field Safety Notice is taken with due consideration of this commitment.

Thank you for your attention and cooperation.

Sincerely,



Becton Dickinson GmbH  
Geschäftsführer: Roland Pflieger  
Sitz: Heidelberg  
Amtsgericht Mannheim HRB 330 707

Tullastr. 8-12  
69126 Heidelberg  
Tel. 06221 305 0  
Fax 06221 305 216

Steuernummer:  
32019/05311  
USt-IdNr.:  
DE143259333

Bankverbindung:  
BNP Paribas Fortis, Belgien  
IBAN: BE78 0017 9083 2386  
SWIFT: GEBABEBB

Die Becton Dickinson GmbH gehört zur BD-Unternehmensgruppe.

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**Actions Required of You:**

1. Carefully read the attached **URGENT FIELD SAFETY NOTICE** (FSN), pages 3-6
2. Identify your customers (Internal and external) impacted by this FSN using the Appendix I affected Product code and Lot Number.
3. Provide your customers (Internal and external) with the information from the FSN. You may need to adapt the text and provide translations for your customers. Your customers are to communicate directly with you and not with BD.
4. Please ensure to complete and return the Distributor Confirmation Form (Appendix II) to BD to acknowledge receipt and understanding of this Field Safety Notice.
5. As a distributor, you are required to perform the Field Safety Corrective Action on all impacted devices in your possession and for all impacted devices at your customers' facilities. Any impacted products received by you shall be returned to BD for scrapping. Please follow instructions accompanying this Field Safety Notice to perform the Field Safety Corrective Action.

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**URGENT FIELD SAFETY NOTICE FOR BD DISTRIBUTOR**

**Affected Product:** BD Micro-Fine Ultra™ 0,25mm (31G) x 5mm

**FSCA-identifier:** BDDC-18-1331-FAC

**Type of action:** Voluntary Product Recall

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Date: September 2018

**ATTENTION:** Distributor

**Details on affected devices:**

Product Name	Catalogue (Ref) No.	Lot No.	Expiration Date
BD Micro-Fine Ultra™ 0,25mm (31G) x 5mm	325104	8149886	31 May 2023

Dear valued customer,

BD is conducting a voluntary field safety corrective action for BD Micro-Fine Ultra™ 0,25mm (31G) x 5mm, lot number 8149886 labeled with a 5 years expiration date.

**Description of the problem:**

The pen needles are being recalled due to cannula protruding through the inner shield component observed during packaging operation. No adverse event has been reported for this issue at this time.



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The defect observed may result in a fragment of the cannula itself breaking off during use, with the potential to remain embedded in the skin of the pen needle user.

The risk of needle breaks in the skin requiring intervention is a low-risk procedure with minor non-permanent injury and is therefore considered moderate in severity.

Transient hyperglycemia, considered as limited in severity, may occur if the needle breaks before/during the injection and a full dose is not delivered or if the patient identifies the defect, prior to use and requires time to procure another pen needle device.

The affected lot is listed in Appendix I below. Users should stop using these lots immediately.

**Advise on action to be taken:**

The following actions are required of you:

- Immediately review your inventory for the specific Product Code (Ref) and lot number listed below and block the affected products for distribution.
- By using the APG-procedure, a recall information will be published by BD in both "Deutsche Apotheker Zeitung" and "Pharmazeutische Zeitung DAZ/PZ". Pharmacies will return products to their suppliers and suppliers will return products to you.
- If information is requested by pharmacies, inform them by providing a copy of the Field Safety Notice (FSN) to them.
- After finalization of the recall, the products will be returned to BD for scrapping.
- Maintain all records associated with this FSCA.

**Contact reference person:**

If you have any questions, or would like to discuss this issue further, please feel free to contact your local BD Key Account Manager:

Danilo Kiese  
Email: danilo.kiese @bd.com  
Phone number: (+49)01.72 74.49.027

We confirm that the appropriate regulatory agencies have been informed of these actions.

The safety and well-being of patients and healthcare workers is the primary objective for BD and we aim to ensure that only the highest quality product is used by our customers. 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.



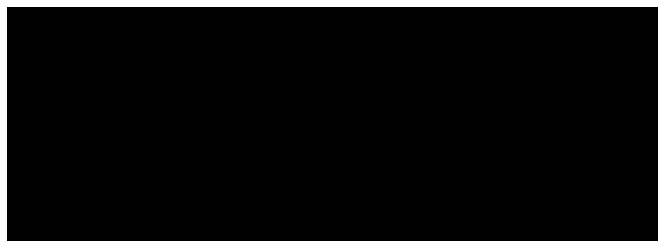
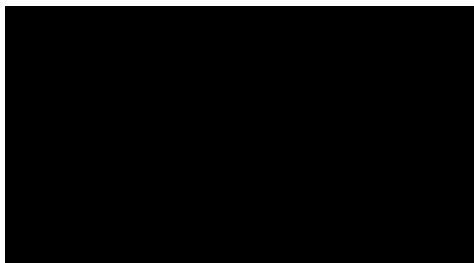
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Yours sincerely,



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**Appendix I: Affected Product Code and Lot Number:**

Product Name	Catalogue (Ref) No.	Lot No.	Expiration Date
BD Micro-Fine Ultra™ 0,25mm (31G) x 5mm	325104	8149886	31 May 2023

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**Appendix II - Distributor Confirmation Form**

**URGENT FIELD SAFETY NOTICE – Acknowledgement Form**

Product Name: BD Micro-Fine Ultra™ 0,25mm (31G) x 5mm  
 Product Code: 325104  
 Lot Number: 8149886  
 FSCA Identifier: BDDC-18-1331-FAC  
 Type of Action: Voluntary Product Recall

<b>Name of Distributor</b>	
<b>Distributor Address</b>	
<b>Telephone Number</b>	
<b>Name</b>	
<b>Signature</b>	
<b>Date</b>	

☐ I have read and understood the contents of this Field Safety Notice and I will execute the actions outlined in it.

**If you have not distributed any affected pen needles listed in this Field Safety Notice**, please confirm the following by checking the box:

☐ I confirm that we have not distributed **any** of the affected pen needles listed in this Field Safety Notice.

Please return your completed Acknowledgement Form to:

[bddiabetes-deutschland@bd.com](mailto:bddiabetes-deutschland@bd.com)