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16th August 2021

URGENT: FIELD SAFETY NOTICE – PI-21-3987

Illinois Bone Marrow Aspiration/ Intraosseous Needle

REF: TIN3015 **LOT: All Lot Numbers**

Type of Action: Product Removal

Attention: Clinical Personnel, Risk Managers,

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

Dear Customer,

BD is conducting a Field Safety Corrective Action to remove all lots of **Illinois Bone Marrow Aspiration/Intraosseous Needles**. According to our distribution records your organisation may have received the impacted product. Product was distributed by BD between August 2016 and June 2021.

Description of the Problem

Based on customer feedback, BD has identified that there is the potential for the needle protector to become dislodged within the packaging which could allow the needle of the device to puncture the packaging, compromising the sterile barrier. In addition, this defect could result in a potential needlestick injury for the caregiver if an exposed needle is not identified.

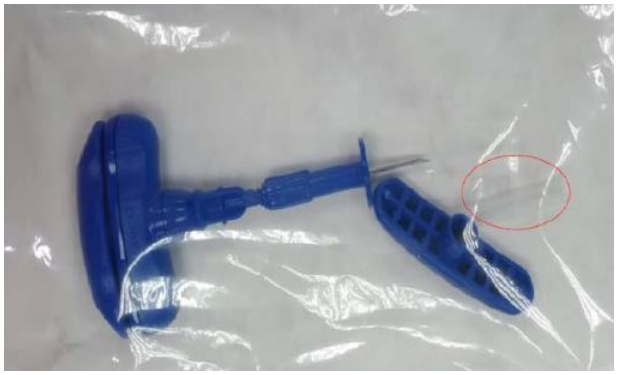

Figure 1: Needle Protector Dislodgement

Figure 2: Hole/Punctured Packaging

BD has identified that this issue is related to all lots produced since July 2016. BD has an on-line tool to support the identification of impacted lot numbers located at: www.bd.com/PI-21-3987

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Clinical Impact

This defect could result in health consequences including a varying degree of infection. Management of the patient, including but not limited to administration of antimicrobial therapy and any patient follow-up, is at the discretion of the treating physician.

Actions taken by BD

1. BD has identified the root cause and is taking corrective actions to prevent recurrence of this issue.

Actions to be taken by the DISTRIBUTOR:

1. Inspect your inventory, locate and quarantine any units of the impacted Lot numbers using the on-line tool at www.bd.com/PI-21-3987 Destroy all impacted product(s).

2. **If you have further distributed the product, identify those facilities and notify them at once of this product removal.**

3. Complete the customer response form on page 4 indicating:
   - the quantities destroyed **OR**
   - that your organisation does not have any impacted units left in inventory

4. Return the completed customer response form with final quantity of destroyed product to <<insert contact details here>> as soon as possible or no later than **24th September 2021**.

5. Contact your local BD representative to discuss product alternatives.

Actions to be taken by the END USER/ HEALTHCARE ORGANISATIONS:

1. Inspect your inventory, locate and quarantine any units of the impacted Lot numbers using the on-line tool at www.bd.com/PI-21-3987 Destroy all impacted product(s).

2. Complete the customer response form on page 4 indicating:
   - the quantities destroyed **OR**
   - that your organisation does not have any impacted units left in inventory

3. **Return the completed customer response form to YOUR DISTRIBUTOR/ PRODUCT SUPPLIER as soon as possible or no later than 10th September 2021.**

Contact Reference Person

If you have any questions about this, please contact your local BD representative or the local BD office on <<insert telephone details here>> or e-mail <<insert contact email address here>>.

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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
Sr. Manager, Post Market Quality
EMEA Quality

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Customer Response Form - PI-21-3987

Illinois Bone Marrow Biopsy/Aspiration Needle

Please read in conjunction with Field Safety Notice PI-21-3987 and return completed and signed form as soon as possible.

- **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 in our possession.

OR

☐ We have the following units of the affected product in our possession and I confirm that the units have been destroyed *(Please complete the table below with the lot number and the number of units destroyed)*

Catalogue (REF) Number	Lot Number:	Number of Units destroyed *(insert quantity below)*

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

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