15th May 2025

URGENT: FIELD SAFETY NOTICE – MDS-24-5154-C

4Fr Single Lumen PowerPICC (SOLO and non-SOLO versions)

REF: See Attachment 1 **Lot Numbers:** See Attachment 1

Type of Action: Product Removal

Attention: Clinical personnel involved in the placement of central vascular devices including but not limited to: Anaesthetist, Intensivists, Interventional Radiology, Vascular Access Specialists & Teams, Risk Managers, Purchasing Managers

***NOTE**: This letter contains additional lot numbers and is an expansion to the letter you may have received in March 2025.*

If you are not impacted by the specific lots being removed as per Attachment 1, this Field Safety Notice contains important information and actions for ALL customers of 4Fr Single-Lumen PowerPICC catheters.

Dear Customer,

Description of the problem

In March 2025, BD issued a global product removal due to an increase of material fatigue leaks on **4Fr single-lumen PowerPICC catheters**, both SOLO and non-SOLO versions, in specific geographies. These leaks are primarily characterised by a transverse/circumferential crack in the catheter tubing (Figure 1).

Based upon customer feedback and continued investigations, BD has further strengthened the specification associated with the MFI to assure product performance which has resulted in an increased scope of the FSN (see attachment 1) and is clarifying its instructions for customers.

Figure 1: Example of transverse/circumferential crack in the catheter tubing

BD's investigation has identified certain factors that contribute to material fatigue leaks in the 4 Fr single-lumen PowerPICC catheter tubing, specifically:

- The resin used to extrude the catheter tubing exceeded our supplier's specification for a material property called melt flow index (MFI). BD's investigation has concluded that a higher MFI could make the PowerPICC catheter tubing more susceptible to leakage when placed under stress.
- Insertion and securement techniques that contradict the PowerPICC IFU requirements, such as the requirement to insert the catheter as close to the zero mark as possible.
    - BD PICCs have a taper design that increases in diameter near the zero-centimeter mark on the device.
    - When using any BD PICC, ensure practice is consistent with BD IFUs for insertion depth and securement, including insertion to the zero mark. Fully insert the PICC as close as possible to the zero-centimeter mark (position B in Figure 2). This allows the kink-resistant, tapered region to be utilised and is associated with lower catheter leakage rates.
    - Select securement devices that can be used consistent with the BD PICC IFU.

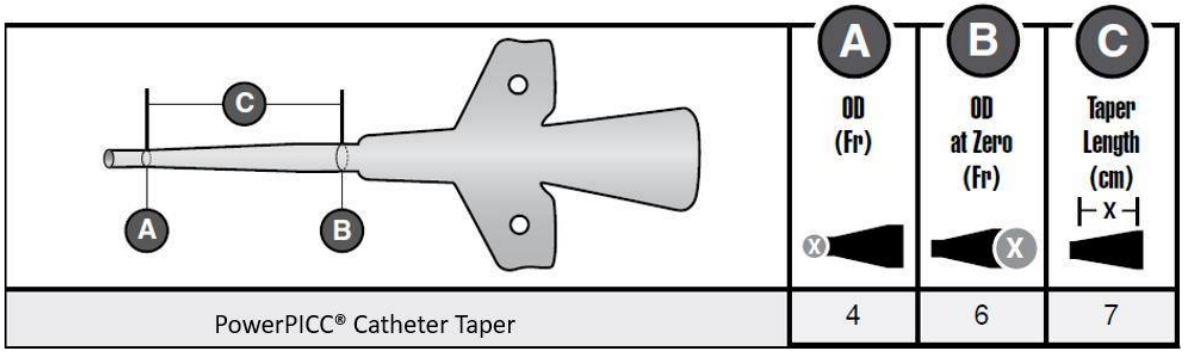

Figure 2: Image of the PowerPICC Taper Region

Clinical risk

The risks associated with material fatigue leakage are as follows: infiltration, extravasation, discomfort, phlebitis, bleeding, air embolism, foreign body embolism, infection and interruption to therapy.

The risks outlined above may require future medical procedures such as retrieval of a foreign body embolism, replacement of the PICC line and other treatments as necessary as deemed appropriate by the health care provider.

Patients and users should observe PICC's for any signs or symptoms that may be consistent with catheter fracture. These signs and symptoms may manifest as, but are not limited to: pain upon infusion, swelling of the arm not related to DVT, inability to withdraw blood, and leakage of infusate around the insertion site. Use clinical judgement to determine if explanting the device is necessary. Any devices remaining in situ should continue to be monitored, looking for signs and symptoms mentioned above. If a catheter fracture is identified, the PICC should be removed as soon as medically possible for the patient.

An increase in material fatigue leakages was identified starting in June 2023. From June 2023 through March 2025, the global complaint rate for material fatigue leaks was 0.065%. All complaints have been assessed for regulatory reportability and reports have been made, as applicable.

Clinical User Actions

Consider the patient's infusion needs, alternative access options and the risks and benefits of continued catheter usage. BD is not recommending to explant product in-situ from any recalled lots unless catheter damage is suspected, as outlined below:

Actions if catheter damage is not suspected:

1. Carefully examine the visible portion of the catheter to assess for any sign of damage to the catheter shaft.
2. Monitor the patient closely for signs and symptoms of catheter damage, such as increased extremity circumference, infusate leakage, or reports of pain.
3. When using any BD PICC ensure practice is consistent with BD Instructions for Use for insertion depth and securement, including insertion to the zero mark. If the IFU for a securement device contradicts the IFU for the BD PICC, follow the IFU for BD's PICCs.

Actions if catheter damage is suspected:

1. Immediately stop any infusion if catheter damage is suspected.
2. Follow your institution's guidelines for catheters with suspected damage.
3. If the catheter is confirmed to have a fracture, the catheter should be removed and an alternative route for access should be obtained.

Action TAKEN by BD

- BD has implemented additional controls around MFI that provides increased level of product assurance.

BD Actions

- BD is removing additional unexpired lots of 4Fr Single Lumen PowerPICC, both SOLO and non-SOLO versions as described in Attachment 1.
- BD is notifying users to ensure practice is consistent with BD Instructions for Use (IFU) for insertion depth and securement.
- BD will provide product replacement or credit for all destroyed products.

Customer Actions:

- Cease use of any unused affected lot numbers of **4Fr Single Lumen PowerPICC.**
- Identify and quarantine all unused affected lot numbers of **4Fr Single Lumen PowerPICC.**
- Make a note of the lot numbers and immediately destroy all unused affected units.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 16th June 2025**.
- Circulate this notice to all those who need to be aware within your organisation or to any organisation where the potentially affected products have been transferred.

- Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Distributor Actions:

- Cease distribution of any unused affected lot numbers of **4Fr Single Lumen PowerPICC**.
- Identify, quarantine, making a note of the lot numbers then destroy all undistributed affected lot numbers of **4Fr Single Lumen PowerPICC.**
- Identify the facilities where you have distributed 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 June**.
- Complete and return the Customer Response Form following completion of your reconciliation activities.
- Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

	End User with Inventory	**End User with ZERO inventory**	**Where to send completed form**
Purchased **directly** from BD	Complete the form in its entirety Upon receipt, BD will process the response, and you will receive **replacements** for unused product	Complete form and check the box indicating "no inventory"	BDFieldActions@bd.com
Purchased from a **distributor/3rd party**	Complete all fields on the form and contact your distributor to arrange for **replacements**	Complete form and check the box indicating "no inventory"	Return the form to your distributor

Contact reference person

If you have any questions about this, please contact your local BD representative or the local BD office.

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,

Kinga Stolinska
Director, Post Market Quality
EMEA Quality

Customer Response Form - MDS-24-5154-C

4Fr Single Lumen PowerPICC (SOLO and non-SOLO versions)

REF: See Attachment 1 **Lot Numbers:** See Attachment 1

Return to BDFieldActions@bd.com as soon as possible or **no later than the 16th June.**

I confirm this Field Safety 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 **Attachment 1** in our facility. Affected product has been used.

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 product as listed in **Attachment 1** 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. **Replacement** product will only be sent on completion and return of this form).*

REF:	Lot Number/s:	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:**
Name of your supplier for this product *(if not direct from BD)*	
Signature:	**Date:**

*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.*