11th March 2025

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

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

REF: See Appendix 1 **Lot Numbers:** See Appendix 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

This letter contains important information which requires your immediate attention.

Dear Customer,

In October 2024, BD issued an advisory Field Safety Notice for unexpired lot numbers of 4Fr Single-Lumen PowerPICC Catheters (SOLO and non-SOLO versions) to inform customers about an observed increase of material fatigue leaks (Figure 1) on the 4Fr Single Lumen PowerPICC catheters in specific geographies.

BD is now conducting a Field Safety Corrective Action to remove **specific** lots of **4Fr Single-Lumen PowerPICC Catheters** listed in Appendix 1.

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

Description of the problem

BD has conducted a comprehensive investigation and has identified that three lots of resin used to extrude the tubing material exceeded our supplier's specification for a material property called Melt Flow Index (MFI). BD's investigation has shown that higher MFI could lead to increased material fatigue leaks. All of the extruded catheters meet BD specifications for dimensions and mechanical properties; however, BD is removing all product from the field that was extruded from resin that exceeded the supplier specification.

Although the increase in complaints is limited to specific geographies, the product with higher MFI has been distributed worldwide, therefore all impacted lots are being removed from the global market.

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

<u>BD has identified two additional contributing factors to the increase in material fatigue leaks seen on the 4Fr Single Lumen PowerPICCs in some geographies. Each factor must be controlled in order to minimize the failures.</u>

Securement Systems:

After engineering analysis and analysis of returned leaking devices, BD has concluded that use of compression style securements has the potential to damage the catheter and cause leaks. A higher number of complaints have been reported from facilities and regions utilizing compression style securement systems. BD is highlighting the following in order to reduce the failures:

- BD strongly recommends the use of adhesive backed securement systems (e.g. Statlock) instead of 'compression style' securement systems.
- Securement systems should be appropriately sized to accommodate the increase in diameter of the catheter in the taper region.

Catheter Insertion and Dressing:

BD PICCs have a reverse taper which increases in diameter near the 0 marking on the device.

- Fully inserting the PICC device into the patient, as close as possible to the zero mark (position B in Figure 2), including the kink-resistant, reverse tapered region at the insertion site, is associated with lower leakage rates. To determine corresponding compression style size see figure 2, which shows that for the 4 Fr PICC, the size will be between 4 to 6 Fr, depending on the position of the securement device relative to the taper.

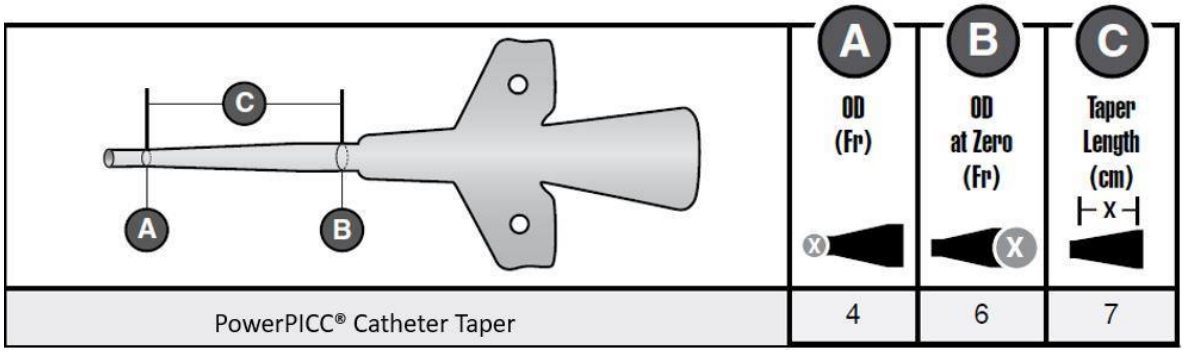

Figure 2: Image of the PowerPICC Taper Region

- Please note, using the J-loop technique when placing or dressing the catheter prevents insertion to the 0 mark and the use of this kink-resistant, reverse tapered region at the insertion site. See Figure 3 for an image of the J-loop. Where possible, refrain from using this technique.

Figure 3: Image of the J-loop

Clinical risk

The current issue is that there has been an increased number of complaints related to PICC fracture and breakage with regards to the 4Fr single lumen PowerPICC and PowerPICC solo. The risks associated with this issue 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 take notice to their PICC lines for any signs or symptoms that may be consistent with catheter fracture or breakage. These signs and symptoms may manifest 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 and any devices remaining in situ should continue to be monitored with current good clinical practice, looking out for the signs and symptoms mentioned above. If a fracture or breakage is noticed, the PICC should be removed as soon as medically possible for the patient.

From June 2023 when BD started to see an increase in complaints through December 2024, the global complaint rate for material fatigue leak is 0.058%. All complaints have been assessed for regulatory reportability and reports have been made, as applicable.

Clinical User Actions

BD is not recommending to explant product in-situ from any lots (including those being recalled). Consider the patient's infusion needs, alternative access options and the risks and benefits of continued catheter usage. The following additional advice is recommended

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. If using a compression style securement device, consider replacing it with an adhesive-backed securement system to reduce the risk of material fatigue. Ensure securement systems are appropriately sized to accommodate the increase in diameter of the catheter in the taper region.
4. Ensure the catheter is positioned correctly, with the kink-resistant, reverse tapered region at the insertion site, to minimize the risk of leaks. Note that if the catheter is currently positioned with the kink-resistant, reverse tapered region external to the patient, it is not advisable to reposition it internally. Instead, be aware that not using this region may increase the risk of leaks. Use clinical judgment to decide whether to continue using the device or to replace it.

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 or break, the catheter should be removed and an alternative route for access should be obtained.

Power Injection Recommendations

Actions if catheter damage is not suspected:

1. If catheter damage is not suspected, weigh the risks and benefits of using the potentially defective device vs. completing the procedure with an alternative device. Consider the patient's condition and the urgency of the high-power injection.
2. Please follow the power injection procedure within the IFU
    - Remove the injection/needleless/end cap from the PowerPICC® catheter.
    - Attach a 10 mL or larger syringe filled with sterile normal saline.
    - Aspirate for adequate blood return and vigorously flush the catheter with the full 10 mL of sterile normal saline. This will ensure the patency of the PowerPICC® catheter and prevent damage to the catheter. Resistance to flushing may indicate partial or complete catheter occlusion. Do not proceed with power injection study until occlusion has been cleared.

   WARNING: Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
3. If replacement or additional access is not feasible and the device must be used, monitor the device closely during the high-power injection and be prepared to address any complications that may arise.

Actions if catheter damage is suspected:

1. Do not use the device for power injection if catheter damage is suspected.

BD Actions

- BD is removing all unexpired lots of 4Fr Single Lumen PowerPICC which exceed the supplier's specification for MFI.
- BD is notifying users that adhesive back securement systems are recommended.
- BD is notifying users that if they do use compression style securement systems, they must be sized appropriately to accommodate the reverse taper.
- BD is notifying customers to insert the catheter to as close as possible to the 0 mark, per the IFU.
- BD has been updating the product IFU with cautions related to the use of compression style securement systems around the taper region of the PICC.
- BD will provide product replacement for all destroyed products.
- BD will continue investigating this issue and will follow up with any additional actions.

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 11th April 2025.**
- 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.
- 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 **11th April 2025.**
- 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
Purchased and supplied through NHS SC	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

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-B

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

REF: See Appendix 1 **Lot Numbers:** See Appendix 1

Return to BDFieldActions@bd.com as soon as possible or **no later than the 11th April 2025**

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 **Appendix 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 **Appendix 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.*

Appendix 1 – Impacted Product Codes / Lot numbers

Manufacturer's SRN: US-MF-000017720

Product Name	REF	Lot No.	Expiration Date DD-MMM-YYYY	UDI
4Fr Single Lumen PowerPICC	2194108	REHT2240	31-May-25	(01)00889989030587(17)250531(10)REHT2240
		REHY2816	31-Oct-25	(01)00889989030587(17)251031(10)REHY2816
	6174108	REGX1802	30-Sep-25	(01)00801741139000(17)250930(10)REGX1802
		REGX2978	30-Sep-25	(01)00801741139000(17)250930(10)REGX2978
		REGX0250	30-Sep-25	(01)00801741139000(17)250930(10)REGX0250
		REGZ0061	31-Oct-25	(01)00801741139000(17)251031(10)REGZ0061
		REHR1412	31-Dec-25	(01)00801741139000(17)251231(10)REHR1412
		REHR0101	31-Mar-26	(01)00801741139000(17)260331(10)REHR0101
	6174355	REGW0745	31-Oct-25	(01)00801741139031(17)251031(10)REGW0745
	6194355	REHU3309	30-Jun-25	(01)00801741139079(17)250630(10)REHU3309
	CK000375	REHY0131	31-Mar-25	(01)00801741102660(17)250331(10)REHY0131