2 International Business Park Road
The Strategy #08-08
Singapore 609930
Registration No. 201114149N
bd.com

PRODUCT RECALL
MDS-24-5154
4Fr Single Lumen PowerPICC

28 May 2025

Dear BD Distributor,

Type of Field Action: Removal (Recall)

Affected Product

Catalog Number	Lot or Serial Number	UDI-DI	Expiration Date	Package Size
3174135	REHS4184	(01)00801741027604(17)260731(10)REHS4184	07/31/2026	5
3174155	REHV2765	(01)00801741027611(17)260731(10)REHV2765	07/31/2026	5
8194335	REJS2465	(01)00801741139130(17)260430(10)REJS2465	04/30/2026	5

Description of the Problem:
BD has seen an increase of material fatigue leaks on 4 Fr single-lumen PowerPICC catheters, both SOLO and non-SOLO versions, in specific geographies. These leaks are primarily characterized by a transverse/circumferential crack in the catheter body (Figure 1).
In March 2025, BD issued a global product removal due to an increase of material fatigue leaks on 4 Fr single-lumen PowerPICC catheters, both SOLO and non-SOLO versions, in specific geographies. These leaks are primarily characterized by a transverse/circumferential crack in the catheter body (Figure 1). Based on further investigation, BD is expanding the product removal to include additional lots of product and clarifying its instructions for customers.

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

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

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- 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 body 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 utilized and is associated with lower catheter leakage rates.
    - Select securement devices that can be used consistent with the BD PICC IFU.

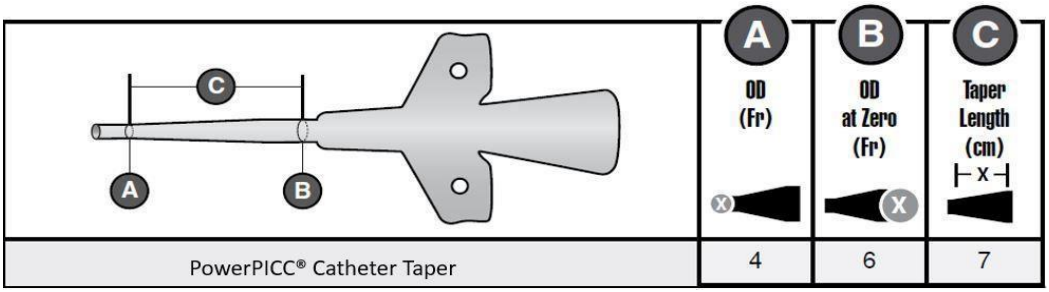

Figure 2: Image of the PowerPICC Taper Region

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 deemed appropriate by the health care provider.

Patients and users should observe PICCs 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.

Complaint & Adverse Event Statement:

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.

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Actions for Clinical Users:

Consider the patient's infusion needs, alternative access options, and the risks and benefits of continued catheter usage. BD is not recommending to explant products 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 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:

We have implemented additional controls around MFI that provides increased level of product assurance.

Actions To Be taken by BD:

- BD is removing additional unexpired lots of 4 Fr. single-lumen PowerPICC, both SOLO and non SOLO versions, as described in letter.
- 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.

Please Take the Following Actions:

1. Please discontinue distribution of product listed in this letter and immediately quarantine and dispose all affected product remaining in your possession in accordance with your local facility's process.
2. Identify all customers within your distribution network that purchased any affected product as defined in this notification. Provide a copy of the attached customer letter to all customers to advise them of this field action notification on BD's behalf.
3. Coordinate customers product return and destruction following your institution's process of destruction.
4. Complete and return the attached Distributor Response Form even if you no longer have any inventory remaining in your facility so that BD may acknowledge your receipt of this notification.
5. Return the signed and completed Distributor Response Form with Distributor Overview, as well as the signed Customer Response Form from all the impacted customers to the BD contact noted on the form.
6. Report any adverse health consequences experienced with the use of this product to BD.

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BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. 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.

Yours Sincerely,

Signed by:
Gaurav Verma
Signer Name: Gaurav Verma
Signing Reason: I approve this document
Signing Time: 28-May-2025 | 12:52:54 AM PDT
AAFA2E5F88004BF59A2BF6F108409CF6

28-May-2025

Gaurav Verma
Director, SEA Quality & Regional RA

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DISTRIBUTOR RESPONSE FORM
MDS-24-5154-EXP
4Fr S/L PowerPICC

Please fill in the information below so that we may acknowledge your receipt of this notification. Complete and return the completed form to **SEA_Quality** SEA_Quality@bd.com **/ local BD representative** by **05 June 2025.**

Please tick as appropriate.

☐ I have read and understood the attached notice taken appropriate actions.

☐ We do not have affected product(s) in our inventory.

☐ We have identified the affected product(s) in our inventory. Affected products have been quarantined until disposal. Upon disposal, we will provide a copy of the Certificate of Destruction/proof of destruction to BD.

The expected date of destruction is: _____.

☐ We have identified all customers that purchased the affected catalog numbers and will notify the affected customers of this notice. The overview of the distribution to the customers are as attached in the Distribution Overview.

Product Description	Catalog No.	Lot No.	Quantity Received (EA)	Quantity Sold (EA)	Remaining Quantity (EA) in inventory to be *destroyed

*** Please provide a copy of the Destruction Certificate/ Proof of Destruction for the disposal of all affected units.**

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Completed by:

Name:	
Signature:	
Date:	
Facility / Address / Telephone Number:	