

30 October 2024

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

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

**REF:** See Appendix 1 **Lot Numbers:** All lot numbers within expiry

**Type of Action:** Advisory

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

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

Dear Customer,

BD is issuing an **advisory** Field Safety Notice for all unexpired lot numbers of **4Fr Single-Lumen PowerPICC Catheters** both SOLO and non-SOLO versions listed in Appendix 1. According to our distribution records, your organisation may have received this product.

**Description of the problem**

BD is releasing an Advisory Field Safety Notice, to inform customers about an observed increase of customer reports in certain countries related to infusate leakage during infusion. These leaks are primarily characterized by a transverse/circumferential crack in the catheter body on the 4 Fr Single-Lumen PowerPICC catheter (Figure 1), both SOLO and non-SOLO versions. The rate of occurrence over the past year is approximately 0.038% globally and is reported to have been noted post implantation at a median catheter implant duration of 44 days (minimum 4 days, maximum 361 days).

The intention of this advisory notice is to inform customers about BD's investigation related to the reported increase of leaks, to provide clinical guidance for suspected catheter damage and usage of the devices and alternative devices.



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

BD has been conducting an investigation to identify root cause(s) for the increase of reported issues in certain countries. To date, BD's investigation has not identified any issues related to manufacturing/supply chain activities and the products meet all established specifications and release criteria. Currently, there is no indication that the increased reports are related to the catheter manufacturing processes, catheter tubing extrusion processes, raw materials, packaging, transportation or sterilisation processes.



BD is continuing to investigate the product material and manufacturing processes. Additionally, BD is conducting further investigations into external securement devices used with the product, clinical practices, patient populations, treatment regimens, infusates, and implant durations amongst other aspects.

### **Clinical risk**

BD has observed an increase in the complaint rate for leakage within certain countries.

BD has received reports of the following harms occurring related to these leaks: extravasation, infiltration, interruption to therapy, foreign body embolism, edema, customer dissatisfaction, bleeding and pain. These harms may have occurred due to the catheter damage.

Other potential harms may include, but are not limited to: infection, phlebitis and air embolism.

The need for the device must be determined by a qualified medical practitioner, and its use and maintenance must follow product specifications and Instructions for Use.

**There is no requirement to remove any implanted device, unless catheter damage is suspected.**

If there are signs and symptoms such as increased extremity circumference, infusate leakage, patient reports of pain, etc. then catheter damage may be suspected and should be further evaluated by a medical professional.

**There is no requirement for customers to return any devices to BD. These products can continue to be used in accordance with the guidance in the IFU and this advisory FSN.**

### **Actions if Catheter damage is suspected**

1. Immediately STOP any infusion.
2. As per common clinical practice, if there is suspicion of a kink or other internal issue with the catheter, consider imaging, as appropriate, to assess the catheter's condition and location. Rule out other issues such as catheter occlusion that may present with similar symptoms (e.g., sluggish or inability to flush and/ or aspirate blood, frequent infusion pump alarms).
3. If the catheter is confirmed to be damaged, remove and replace the device with the appropriate access type, as needed for the patient.
4. Report it as a complaint as per your normal process.

### **Clinical User Actions**

1. Refer to the product Instructions for Use and adhere to all contraindications, warnings, cautions, precautions, and instructions provided by the manufacturer for all infusates, including contrast media.
2. The practitioner may also wish to consider the following alternative products in the Table below. See **Appendix 1** for the impacted product codes and **Appendix 2** for specific country availability. For further clinical information & advice please contact your local clinical/medical representative.



**Current PICCs impacted by field safety notice**

Product Description	Size &OD (mm)	Proximal Reverse Taper	Length (cm)	Number of Lumens	Valved?	Power injectable/ (Power injection rate)	Material
4Fr Single-Lumen PowerPICC SOLO	4Fr (1.44)	Yes	55	1	Yes	Yes (5 mL/s)	Polyurethane
4Fr Single-Lumen PowerPICC	4Fr (1.44)	Yes	55	1	No	Yes (5 mL/s)	Polyurethane

Table 1: Summary of key Characteristics of Impacted PICC

**Alternative PICC options**

Product Description	Size & OD (mm)	Proximal Reverse Taper	Length (cm)	Number of Lumens	Valved?	Power injectable/ (Power injection rate)	Material	Sherlock 3 CG TCS Option?
<u>5 Fr POWER Groshong</u>	<u>5Fr (1.71)</u>	Yes	<u>40</u>	<u>1</u>	<u>Yes</u>	<u>Yes (4 mL/s)</u>	<u>Silicone</u>	<u>Yes</u>
<u>4 Fr Groshong NXT</u>	<u>4Fr (1.40)</u>	No	<u>60</u>	<u>1</u>	<u>Yes</u>	<u>No (NA)</u>	<u>Silicone</u>	<u>Yes</u>
<u>5 Fr POWERPICC SOLO SL</u>	<u>5Fr (1.66)</u>	Yes	<u>55</u>	<u>1</u>	<u>Yes</u>	<u>Yes (5 mL/s)</u>	<u>Polyurethane</u>	<u>Yes</u>
<u>5 Fr POWERPICC SOLO DL</u>	<u>5Fr (1.81)</u>	Yes	<u>55</u>	<u>2</u>	<u>Yes</u>	<u>Yes (5 mL/s)</u>	<u>Polyurethane</u>	<u>Yes</u>
<u>5 Fr POWERPICC SL</u>	<u>5Fr (1.66)</u>	Yes	<u>55</u>	<u>1</u>	<u>No</u>	<u>Yes (5mL/s)</u>	<u>Polyurethane</u>	<u>Yes</u>
<u>5 Fr POWERPICC DL</u>	<u>5Fr (1.81)</u>	Yes	<u>55</u>	<u>2</u>	<u>No</u>	<u>Yes (5mL/s)</u>	<u>Polyurethane</u>	<u>Yes</u>

Table 2: Summary of key Characteristics of Alternate PICC

**BD Actions:**

BD will continue investigating this issue and will follow up with any additional actions if needed.

**Customer Actions:**

- Review the information in **Appendix 1** to determine if the 4 Fr Single-Lumen PowerPICC catheters (SOLO and non-SOLO versions) in your possession are listed.
- Circulate this notice to all those who need to be aware within your organisation or to any organisation where the potentially affected product has been transferred.
- If you experience any issues, please report as a complaint as per your normal process.
- There is no requirement for customers to return any devices to BD. These products can continue to be used in accordance with the guidance in the IFU and this advisory FSN,



however if you wish to discuss replacement of the devices with alternate devices, please contact your local BD representative.

- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 28<sup>th</sup> November 2024.**

**Distributor Actions:**

- Review the information in **Appendix 1** and identify the facilities where you have distributed affected products and notify them immediately of this notice.
  - Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes by **28<sup>th</sup> November 2024.**
- Complete and return the Customer Response Form following completion of your reconciliation activities.
- If you experience any issues, please report as a complaint as per your normal process.

	<b>End User with Inventory</b>	<b>End User with ZERO inventory</b>	<b>Where to send completed form</b>
Purchased <b>directly</b> from BD	Complete the form in its entirety and ensure that all recommended actions have been implemented as required	Complete the form in its entirety and retain a copy of this notification for your records	<a href="mailto:BDFieldActions@bd.com">BDFieldActions@bd.com</a>
Purchased from a <b>distributor/3<sup>rd</sup> party</b>	Complete the form in its entirety and ensure that all recommended actions have been implemented as required	Complete the form in its entirety and retain a copy of this notification for your records	Return the form to your distributor/3 <sup>rd</sup> party

**Contact reference person**

If you have any questions, 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



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## Customer Response Form – MDS-24-5154

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

REF: See Appendix 1 **Lot Numbers:** All lot numbers within expiry

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Return to [BDFieldActions@bd.com](mailto:BDFieldActions@bd.com) as soon as possible or **no later than the 28th November 2024.**

**By signing below, you confirm this Field Safety Notice has been read, understood and that all recommended actions have been implemented as required.**

<b>Account/Organisation Name:</b>	
<b>Department</b> <i>(if applicable):</i>	
<b>Address:</b>	
<b>Postcode:</b>	<b>City:</b>
<b>Contact Name:</b>	
<b>Job Title:</b>	
<b>Contact Telephone Number:</b>	<b>Contact E-mail Address:</b>
<b>Name of your supplier for this product</b> <i>(if not direct from BD)*</i>	
<b>Signature:</b>	<b>Date:</b>

*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/3<sup>rd</sup> party, please return your completed form to that organisation for reconciliation purposes.*



## Appendix 1 – Impacted Product Codes

**Manufacturer's SRN:** US-MF-000017720

Product Description	Product Code (Ref)	UDI	Size & OD (mm)	Length (cm)	Number of Lumens	Valved?	Power injectable/ (Power injection rate)	Material	Sherlock 3 CG TCS?
4Fr Single-Lumen PowerPICC SOLO	2194108	00889989030587	4Fr (1.44)	55	1	Yes	Yes (5 mL/s)	Polyurethane	Yes
	CK000375	00801741102660							Yes
	6194118	00801741139055							No
	6194335	00801741139062							No
	6194355	00801741139079							No
	6194108	00801741139048							No
4Fr Single-Lumen PowerPICC	CK000388	00801741102790	4Fr (1.44)	55	1	No	Yes (5 mL/s)	Polyurethane	Yes
	2174108	00801741138966							Yes
	6174108	00801741139000							No
	6174118	00801741139017							No
	6174355	00801741139031							No
	22184118	00801741121579							Yes
	6174335	00801741139024							No



Appendix 2 – Alternative PICC Product Codes by Country

REF	CK000517	CK000516	2195108	22195118	2295108	CK000377	22295118	22295208F	22295118F	2175108	22185118	2275108	22285118	CK000390	22275208F
	POWERGROSHONG 5 FR SL WITH SHERLOCK 3CG TPS BEDSIDE TRAY	GROSHONG NXT CLEARVUE 4 FR SL WITH SHERLOCK 3CG TPS BEDSIDE TRAY	POWERPICC SOLO 5 FR SL 3CG FULL TRAY	POWERPICC SOLO 5 FR SL 3CG BASIC TRAY	POWERPICC SOLO 5 FR DL 3CG FULL TRAY	POWERPICC SOLO 5 FR DL 3CG BEDSIDE TRAY	POWERPICC SOLO 5 FR DL 3CG BASIC TRAY	POWERPICC SOLO FT 5 FR DL 3CG BEDSIDE TRAY	POWERPICC SOLO FT 5 FR DL 3CG BASIC TRAY	POWERPICC 5 FR SL 3CG FULL TRAY	POWERPICC 5 FR SL 3CG BASIC TRAY	POWERPICC 5 FR DL 3CG FULL TRAY	POWERPICC 5 FR DL 3CG BASIC TRAY	POWERPICC 5 FR DL 3CG BEDSIDE TRAY	POWERPICC FT 5 FR DL 3CG BEDSIDE TRAY
UK	✓	✓	✓	×	✓	✓	×	✓	✓	✓	✓	✓	✓	✓	✓
Ireland	✓	✓	✓	×	✓	✓	×	✓	✓	✓	✓	✓	✓	✓	✓
Spain	×	×	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	✓	×	✓
Italy	✓	✓	✓	✓	✓	×	×	×	×	✓	×	✓	×	×	×
Sweden	×	×	✓	✓	✓	×	✓	×	✓	✓	✓	✓	✓	×	×
Denmark	×	×	✓	✓	✓	×	✓	×	✓	✓	✓	✓	✓	×	×
Norway	×	×	✓	✓	✓	×	✓	×	✓	✓	✓	✓	✓	×	×
Finland	×	×	✓	✓	✓	×	✓	×	✓	✓	✓	✓	✓	×	✓
Iceland	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
France	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×
Germany	×	×	✓	✓	✓	×	✓	×	✓	✓	✓	✓	✓	×	×
Austria	×	×	✓	✓	✓	×	✓	×	✓	✓	✓	✓	✓	×	×
Belgium	×	×	✓	✓	✓	×	✓	×	✓	✓	✓	✓	✓	×	×
Netherlands	×	×	✓	✓	✓	×	✓	×	✓	✓	✓	✓	✓	×	×
Luxembourg	×	×	✓	✓	✓	×	✓	×	✓	✓	✓	✓	×	×	×
Portugal	×	×	✓	✓	✓	×	✓	×	✓	✓	✓	✓	✓	×	×
Greece	×	×	✓	✓	✓	×	✓	×	✓	✓	✓	✓	✓	×	×
Switzerland	×	×	✓	✓	✓	×	×	×	✓	✓	✓	✓	✓	×	×
Poland	×	×	✓	×	×	✓	×	×	×	×	×	×	×	×	×
Hungary	×	×	✓	×	✓	×	×	×	×	✓	×	×	×	×	×
Czech Republic	×	×	✓	×	✓	×	×	×	×	×	×	×	×	×	×
Slovakia	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×
Slovenia	×	×	✓	×	✓	×	×	×	×	×	×	×	×	×	×
Croatia	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×