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?
5 Fr POWER Groshong	5Fr (1.71)	Yes	40	1	Yes	Yes (4 mL/s)	Silicone	Yes
4 Fr Groshong NXT	4Fr (1.40)	No	60	1	Yes	No (NA)	Silicone	Yes
5 Fr POWERPICC SOLO SL	5Fr (1.66)	Yes	55	1	Yes	Yes (5 mL/s)	Polyurethane	Yes
5 Fr POWERPICC SOLO DL	5Fr (1.81)	Yes	55	2	Yes	Yes (5 mL/s)	Polyurethane	Yes
5 Fr POWERPICC SL	5Fr (1.66)	Yes	55	1	No	Yes (5mL/s)	Polyurethane	Yes
5 Fr POWERPICC DL	5Fr (1.81)	Yes	55	2	No	Yes (5mL/s)	Polyurethane	Yes

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 28th 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 **28th 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.

	End User with Inventory	End User with ZERO inventory	Where to send completed form
Purchased **directly** 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	BDFieldActions@bd.com
Purchased from a **distributor/3rd party**	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/3rd 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

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

Return to 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.

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

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