02 December 2024

Dear Product Safety Advisers; Clinical Product Advisers

Product Safety Alert

Medsafe Ref: #34226

BD Ref: MDS-24-5154

Product Name (Brand Name as per labelling)	**Catalog No.**	**Lot No.**	**WAND**
4Fr Single Lumen PowerPICC Basic	6174118	All	110222-WAND-6AMC6O
4Fr Single Lumen PowerPICC IR 135cm	6174335		110222-WAND-6AMC6O
4Fr Single Lumen PowerPICC SOLO Basic	6194118		111101-WAND-6C4DDR
4Fr Single Lumen PowerPICC SOLO IR 70cm	6194355		111101-WAND-6C4DDR
4Fr Single Lumen PowerPICC SOLO IR 135cm	6194335		111101-WAND-6C4DDR
4Fr Single Lumen PowerPICC Sherlock TCS	22184118		110222-WAND-6AMC6O
4Fr Single Lumen PowerPICC SOLO Sherlock TCS	22194118		111101-WAND-6C4DDR

Following consultation with MedSafe, BD is initiating an Urgent Product Safety Alert relating to the above-mentioned products.

Issue:

BD is releasing a Product Safety Alert, to inform customers about an observed increase of customer reports in certain countries related to infusate leakage during infusion. These leaks are primarily characterised by a transverse/circumferential crack in the catheter body on the 4 Fr Single-Lumen PowerPICC catheters (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).

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

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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.

Health hazard Evaluation / Potential 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.

Actions required by Clinical Users

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. Complete the attached Acknowledgement Form and email the completed form to recall@healthcarelogistics.co.nz whether-or-not you have any of the impacted product so that BD may acknowledge your receipt of this notification.
3. The practitioner may also wish to consider the following alternative products in the Table below.

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Current PICCs impacted by this product advisory

Product Name	Catalog No.
4Fr Single Lumen PowerPICC Basic	6174118
4Fr Single Lumen PowerPICC IR 135cm	6174335
4Fr Single Lumen PowerPICC SOLO Basic	6194118
4Fr Single Lumen PowerPICC SOLO IR 70cm	6194355
4Fr Single Lumen PowerPICC SOLO IR 135cm	6194335
4Fr Single Lumen PowerPICC Sherlock TCS	22184118
4Fr Single Lumen PowerPICC SOLO Sherlock TCS	22194118

Alternative PICC options

Product Name	Catalog No.
3Fr Single Lumen PowerPICC Sherlock TCS	22173118
4Fr Dual Lumen PowerPICC Sherlock TCS	22274118
3Fr Single Lumen PowerPICC Basic	66173118
3Fr Single Lumen PowerPICC IR 70cm	66173355
3Fr Single Lumen PowerPICC IR 135cm	66173335
4Fr Dual Lumen PowerPICC Basic	66274118
4Fr Dual Lumen PowerPICC IR 70cm	66274355
4Fr Dual Lumen PowerPICC IR 135cm	66274335
5Fr Single Lumen PowerPICC Basic	6175118
5Fr Single Lumen PowerPICC IR 70cm	6175355
5Fr Single Lumen PowerPICC IR 135cm	6175335
5Fr Dual Lumen PowerPICC SOLO Basic	6295118
5Fr Dual Lumen PowerPICC SOLO IR 70cm	6295355
5Fr Dual Lumen PowerPICC SOLO IR 135cm	6295335

Please advise your BD Sales Associate of your preferred alternative to ensure that we hold sufficient stock levels of each product.

Actions Taken by BD:

- In addition to the alternatives listed above, BD are also working with our manufacturers worldwide to identify further alternative options in the PowerPICC SOLO range.
- BD will continue investigating this issue and will follow up with any additional actions if needed.

Should you require further information or information on substitute devices at this time, please do not hesitate to contact your BD Sales Associate.

Please complete the attached Acknowledgement Form and email the completed form to recall@healthcarelogistics.co.nz whether-or-not you have any of the impacted product so that BD may acknowledge your receipt of this notification.

This action has been undertaken following consultation with Medsafe.

Yours sincerely,

Signed by:
Matt Taylor
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Matt Taylor
National Quality Manager
Healthcare Logistics NZ

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