

Supply Chain Product

24 February 2025

Power PICC SOLO™2 – 4FR products

NEW Option 2

This information is related to product complaints received and the provincial collaborative response, for your awareness:

- Multiple product complaints have been received about leaking observed below the PICC insertion site
- Holes have been observed between 4cm-15cm marks, weeks to months post-insertion
- Multiple lot #'s affected
- BD is actively investigating and no root cause has been confirmed at this time



The following BD product codes are <u>possibly</u> affected: ***Note Southern Health-Santé Sud only uses the first item, SAP 288341. our stock SKU 00550:

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	SAP#	BD#	Description			
	288341	2194108	Power PICC Solo™2 4FR Single Lumen Cath, Full Tray w/			
			Sherlock ® TLS Stylet			
	287879	1194118	Power PICC Solo™2 4FR Single Lumen Catheter Nursing Basic			
			Tray w/Microintroducer(3CG)			
ĺ	367896	9194118	Power PICC Solo™2 4FR Single Lumen Cath, Basic Tray w/			
			Sherlock ® TLS Stylet			
	214227	3194118	Power PICC Solo™2 4FR Single Lumen Catheter Basic Tray			

What to document if a patient presents with a leaking PICC:

- Retain the defective product for inspection by BD
- Record the lot #
- Identify and record at the centimetre mark where the leak has been detected
- Complete a Product Complaint Form
- Contact Amanda Kirdei at BD to discuss and complete the BD Product Incident Report Survey
- Note- Vendor requests that if an X-ray was taken based on clinical indications that any observations related to the PICC be included in the complaint description. For example, a bend or kink in the catheter

Risk Mitigation Strategy:

- ASAP replace inventory for any of the BD products listed above with an alternate, considering the following options outlined, which are available to order as required
- Once replacement product is on-site and available for use, work with site Material Managers to quarantine affected BD product codes



Supply Chain Product Safety Alert UPDATE

24 February 2025

Power PICC SOLO™2 - 4FR products

PICC Inserters to select what they require, to meet the clinical needs of clients:

Note Option 1B has been received at Portage District Hospital and is being trialed

	SAP#	Product Code/ Supplier	Description	Clinical Considerations
Option 1A	376540	1174118 BD	TRAY POWERPICC BASIC CATH SNGL LUM 4FR (Basic Kit, PICC 4 FR Single Lumen, Proximal Clamps, Polyurethane, Power injection, 55 cm wire)	Nursing: -Non-Valved -works with ultrasound/navigation -Heparin may be required-refer to site policy for locking this device
Option 1B	376562	2174108 BD	TRAY POWERPICC CATH SNGL LUM MAX BARRIER4FR (Max Barrier Kit, PICC 4FR Single Lumen, Proximal Clamps Polyurethane, Power injection, 55 cm wire w/ additional procedure supplies)	Nursing: -Non-Valved -works with ultrasound/navigation -Heparin may be required-refer to site policy for locking this device
New Option 2***	376475 + 211601	H965251220 H965459161 Angiodynamics via CHS Ltd.	KIT PICC SNGL LUMEN VALVE 4FR 145CM WIRE (XCELA PASV 4FR, 55CM IR, 145 Nitinol Wire, PG) KIT MICROINTRODUCER 35CM WIRE 5FR 5CM	Clinical PICC Inserter: -Valved -change out Long Nitinol Wire (145 cm) and use the 35cm wire from micro-introducer kit - compatible w/navigation - Endexo technology (thromboresistant)



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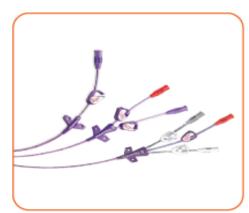
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PowerPICC™ Catheter Care and maintenance

Dressing change:

- Use aseptic technique or aseptic no-touch technique for application of dressing and securement.¹
- Change transparent every 7 days and when compromised (e.g. loose, wet or soiled).
- Change non-transparent dressing every 2 days if unable to assess site.
- Change StatLock™ Stabilization Device at least every 7 days.
- During all dressing changes, assess the external length of the catheter to determine if migration of the catheter has occurred.
- Change add-on devices at least every 4-7 days, with every new VAD, if accidentally removed, contaminated, or if blood residue remains.



Flushing and locking:

- Flush each catheter lumen with 10 mL sterile normal saline every 12 hours and before and after each use.
- Flush with 20 mL after blood therapy or blood collection.
- Flush with 10 mL barrel-sized syringe using pulsatile or push pause technique.
- Do not use a syringe smaller than 10 mL to flush or when confirming patency.
- Do not use excess pressure to flush, if resistance is met, follow organizational policy for dearing occluded catheters.
- Lock each catheter lumen according to organizational policy.

Catheter removal:

- When clinically indicated, based on assessment.
- Therapy is completed.
- Unresolved clinical signs and symptoms of complications or dysfunction.

Canadian Vascular Access Association. (2019). Canadian Vascular Access and Infusion Therapy Guidelines. Pembroke, ON: Pappin Communications.

Indications for Use: The PowerPICC™ Catheter is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, and power injection of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion, or therapy use a 4 French or larger catheter. The maximum flow rate recommended infusion rate is 5mL/sec for power injection of contrast media. For central venous pressure monitoring with this line it is recommended that a catheter lumen of 20 gauge or larger be used.

Please consult product labels and inserts for any indications, contra-indications, hazards, warnings, precautions and instructions for use.

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Care and Maintenance

Xcela PICC with PASV Valve Technology

Providing power injection capability with the performance of the PASV Valve Technology.

REFER TO DIRECTIONS FOR USE PROVIDED WITH THE PRODUCT FOR COMPLETE INSTRUCTIONS

PASV' Valve Technology is Designed to Automatically:







SUGGESTED FLUSHING PROTOCOL

Flush Xcela* PICC lumens and follow institutional protocol for changing or replacing needleless connectors.

- 1. Using a 10 mL syringe or larger, flush each lumen with 10 mL sterile
- 2. Flush each lumen using a "pulse" or "stop/start" technique.1
- 3. Disconnect the syringe.

SUGGESTED VENOUS BLOOD SAMPLING PROTOCOL

- Flush the selected lumen with 10 mL of sterile normal saline.
- 3. Using the same syringe, draw 3 to
- Disconnect and discard the syringe.
 7. Disconnect the syringe.
- 1, Stop administration of infusates. 5. Attach a second 10 mL syringe or collection set and slowly aspirate the blood sample.
 - 6. Using a 10 mL syringe or larger, 5 mL of blood by slowly pulling and holding the plunger, allowing the PASV Valve to open.

 flush the selected lumen with a minimum of 20 mL of sterile normal saline using a "pulse" or "stop/ start" technique.

PATIENT EDUCATION

Important information to communicate to patients:

- . Complete Travel Card included in Patient Guide and carry at all times.
- glycol-containing ointments to clean the catheter.
- · Protect dressing from exposure
- . If dressing becomes wet or loose, have it changed.
- catheter hub at all times.
 - . Notify healthcare provider immediately if catheter is damaged.

IMPORTANT CARE GUIDELINES

Always use aseptic technique.

Catheter Care

- . The PASV Valve is contained within the PICC hub acting as the clamp. PICCs containing this valve do not require clamps (Figures 1-2).
- . Do not use clamps, hemostats or other similar implements to tighten or remove accessories.
- Use a 10 mL syringe or larger.
- When administering care, inspect visible components for damage.
- . At each treatment, verify that external catheter length matches measurement recorded upon insertion.

Site Care

- · If alcohol-based solutions are used, allow them to completely dry.
- Assess site for potential infection. If redness, swelling or drainage is observed, notify physician.
- . Cover site with occlusive dressing applied per institutional protocol Keep dressing clean, dry and intact at all times (Figure 3).
- · Leave extension tubes, hubs and connectors exposed.
- Do not use scissors to remove dressing as this may possibly cut or damage the catheter.







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