

Supply Chain Product Safety Alert

Sept. 24, 2024

This information is related to product complaints received and a provincial sku00550 response for your awareness.

What is the Problem? multiple reports received regarding breakage/leaking of the BD Product Code: 2194108: 4 FR Solo Single Lumen Power PIC Catheters, Max Barrier Kit with Sherlock TLS

Stylet, SAP # 288341. Multiple Lot numbers involved. BD is investigating. No root cause confirmed at this time. Leaking observed weeks or months following insertion.

There were similar complaints in 2023 with other BD 4FR products. As a precaution these are also in scope of this Alert.

SAP #	BD #	Description	
287879	1194118	Nursing Basic Tray Solo 2- 4FR with Microintroducer (3CG)	NS
367896	9194118	Basic Tray Solo 2- 4FR with Sherlock TLS Stylet	NS
214227	3194118	Basic Tray (Kit) Solo 2 4FR	NS

What you need to do if you have this experience:

- Retain the defective product for inspection by BD
- Record the lot #
- If possible, take an X-ray prior to removal
- Identify and record at the centimeter mark the crack/leak is detected
- Complete a Product Complaint Form

Risk Mitigation Strategy:

- ASAP possible replace inventory for any of the BD products listed above with an alternate considering the following options which are available to order as required.
- Work with site Material Managers to **quarantine** any **BD Product Code: 2194108** once replacement product is available for use.
 SKU00550)

PICC Inserters to select what they require to meet the clinical needs

	SAP #	Product Code	Description	What's Different from original	Precautions
Option 1	No SAP #-free text	1174118 (BD Power PICC)	Basic Tray, PICC 4 FR Single Lumen, Proximal Clamps, Polyurethane, Power injection, 55 cm wire.	Basic Tray- Non Valved Catheter	Attn: Nursing- <u>Non-</u> <u>Valved,</u> Heparin required
Option 2 ***	214680	H965458910 (Angiodynami cs)	Kit, 4 Fr Single Lumen MST Kit Valved Bio- Stable PICC, 70 cm Nitinol Wire	Longer wire, Not compatible with ultrasound/na vigation	Attn: Clinical PICC Inserter- <u>Valved</u> Long Wire (70 cm) with Nitinol and Blind insertion.

