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14th July 2022

URGENT: FIELD SAFETY NOTICE – MDS-22-4427 UPDATED

BD Venflon™ Pro Safety (VPS) Needle Protected IV Cannula

REF: See Appendix 1 **Lot Numbers:** See Appendix 1

Type of Action: Product Removal

Attention: Clinical Personnel, Risk Managers, Pharmacists, Purchasing Managers

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

Dear Customer,

In April 2022, BD issued a product removal Field Safety Notice (MDS-22-4427) for two lots of BD Venflon™ Pro Safety (VPS) Needle Protected IV Cannula to affected customers (REF: 393222, lots 1274661, 1274662). Since the distribution of that Field Safety Notice, BD has identified further product codes and lots of BD Venflon™ Pro Safety (VPS) Needle Protected IV Cannula which may also exhibit the reported defect. According to our distribution records, your organisation may have received the impacted product.

This product removal is limited to the product codes and lot numbers listed in Appendix 1. No other product codes or lot numbers are affected by this field action.

Description of the problem

BD had confirmed an increase in reports for leakage from the end cap, as shown in Image 1 below, for BD Venflon™ Pro Safety (VPS) Needle Protected IV Cannula, during the period of December 2021 to March 2022. As of June 2022, there have been an additional fourteen complaints reported in May 2022 related to leaks from the luer cone tip of the end cap. These complaints are not associated with the lots from the original Field Safety Notice released in April 2022.

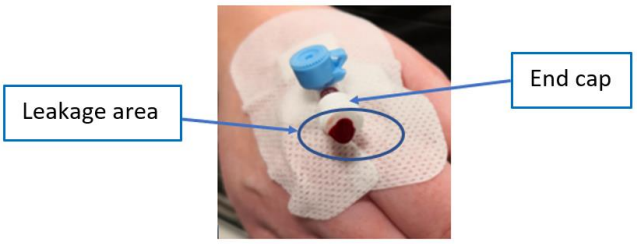

Image 1: Leakage location

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Clinical risk

The clinical risk associated with this defect remains unchanged from the previous Field Safety Notice. The amount of reported blood leakage has been small and easily visualized, reducing the potential risks of blood loss and blood exposure. However, leakage from the end cap could result in acute blood loss by the patient. The significance of this blood loss would be affected by the amount of blood loss experienced by the individual patient. Effects could range from no effect in the instance of minimal blood loss, to significant cardiovascular instability in the instance of severe blood loss.

Leakage from the end cap could also decrease delivery of medications and/or blood products being provided through the IV catheter port. Catheters are routinely used in healthcare settings under the guidance of clinicians; therefore, it would be expected that the leakage would be promptly recognized and treated.

BD has received complaints and reported adverse events for this issue, none of which reported or resulted in serious harm. No additional follow-up activities are required for patients already treated with the device.

Actions taken by BD

Investigation initially identified a specific molding cavity defect and corrective actions were implemented. Further actions have been identified and are being implemented in relation to the molding process.

Actions for Clinical Users

For Clinical Users:

For devices *in situ* where the end cap is being used, replace with a stand-alone end cap or connect an extension set per your clinical judgment based on patient condition, use case and hospital policy.

Actions for customers to take:

BD requires that the following actions are taken:

1. Inspect your inventory, locate and quarantine any units of the impacted lot numbers. Make a note of these lot numbers, then destroy all affected product. For units destroyed, replacement devices will be sent.

2. If you have further distributed the product, identify those facilities, notify them at once of this product removal and have them destroy the affected product.

3. If you experience any issues with the BD Venflon™ Pro Safety (VPS) Needle Protected IV Cannula, report as a complaint as per your normal process.

4. Complete and sign the Customer Response Form on page 4 and return it to <<insert contact details here>> **as soon as possible or no later than 9th August 2022**, indicating the following:
    - the number of units destroyed, **OR**
    - that your organisation does not have any impacted units left in inventory.

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Note: If you no longer have or use the product, it is still important that you return the Customer Response Form for our reconciliation purposes**.**

Contact reference person

If you have any questions about this, please contact your local BD representative or the local BD office on <<insert telephone details here>> or e-mail <<insert contact email address here>>.

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,

Lorna Darrock
Sr. Manager, Post Market Quality
EMEA Quality

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Customer Response Form - MDS-22-4427

BD Venflon™ Pro Safety (VPS) Needle Protected IV Cannula

REF: 393222 **Lot Numbers:** See Appendix 1

Return to << insert email address>> as soon as possible or **no later than the 9th August 2022**

I confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Tick the appropriate box below:

☐ We do not have any of the affected product as listed in Appendix 1 in our possession.

OR

☐ We have units of the affected product as listed in Appendix 1 and we confirm that the units have been destroyed.

(Please complete the table in Appendix 1 with the number of units destroyed for each applicable lot number. Replacement devices will only be sent on completion and return of this form with Appendix 1).

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*

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Appendix 1 – Impacted Product List

Product Code (REF)	Product Description	Lot Number	Units destroyed *(Insert unit quantity below)*
393222	Venflon Pro Safety 22GA 0.9 mm x 25 mm	1274661	
		1274662	
		1320856	
		1320861	
		1320873	
		1323788	
		1323799	
		1323804	
		1323805	
		1323813	
		1357379	
		1357389	
		1357400	
		2022910	
393224	Venflon Pro Safety 20GA 1.1 mm x 32 mm	1320894	
		1320905	
		1320907	
		1320914	
		1357431	
		1357432	
		1357433	
		1357434	
		1357438	
		1359608	
393226	Venflon Pro Safety 18GA 1.3 mm x 32 mm	1323873	
		1323876	
		1323888	
		1359630	
		1359635	
		1359673	
393227	Venflon Pro Safety 18GA 1.3 mm x 45 mm	1323891	
		2022008	
		2022011	
393282	Venflon Pro Safety 18GA 1.3 mm x 32mm INSTAFLASH	1356889	
393228	Venflon Pro Safety 17GA 1.5 mm x 45 mm	1359681	
393229	Venflon Pro Safety 16GA 1.8 mm x 45 mm	1359685	
393230	Venflon Pro Safety 14GA 2.0 mm x 45 mm	1323907	