BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 Fax:
+41 21 556 30 99
www.BD.com

17th May 2021

URGENT: FIELD SAFETY NOTICE – MDS-21-4111

BD Venflon Pro™ IV Cannula

REF & Lot Numbers: See Appendix 1

Type of Action: Product Removal

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

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

Dear Customer,

BD is conducting a Field Safety Corrective Action to remove the BD Venflon Pro™ IV Cannula. This product removal is limited to the catalogue numbers (REF) in Appendix 1. BD has an on-line tool to support the identification of impacted lot numbers located at: http://www.bd.com/MDS-21-4111. No other product codes or lot numbers are affected.

According to our distribution records your organisation may have received the impacted product between <<insert date>> and <<insert date>>.

Description of the Problem

BD has confirmed an increase in reports for leakage from the injection port of the BD Venflon™ Pro IV Cannula (Figure 1) when sterilized by ETO (Figure 2). The identified root cause is the change to EtO sterilization.

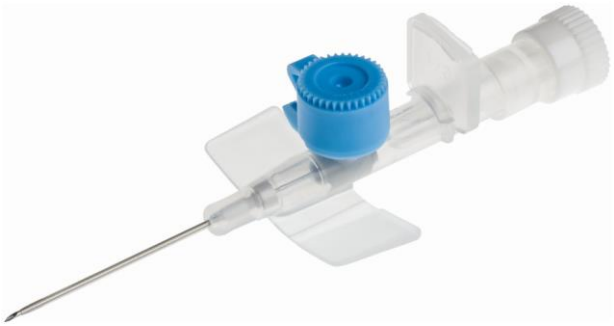

Figure 1: Representative image of BD Venflon™ Pro™ IV Cannula

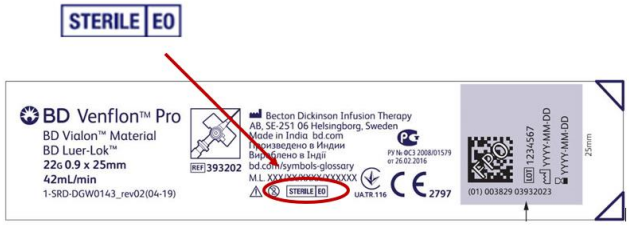

Figure 2: Representative image of product labelling indicating method of EtO sterilisation

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Clinical Impact

The leakage could result in a critical clinical impact, if the leak is undetected for a period of time, as it has the potential to result in blood loss or inadequate infusion of the infusate and this could result is serious harm or even life-threatening conditions or death.

No additional follow-up activities are required for patients already treated with the devices.

Corrective Actions by BD

BD is taking steps to investigate and implement an appropriate corrective action plan which is expected to lead to supply disruption in the long term.

During this supply disruption, please contact your local BD representative to discuss the availability of product alternatives.

Advice on actions to be taken by the Customer:

1. Identify, quarantine, and destroy any of the impacted lot in your inventory.
2. If you have further distributed the product, please identify those facilities, notify them at once of this product removal and have them destroy the affected product.
3. Complete the customer response form on page 3 indicating:
   - the quantities destroyed **OR**
   - that your organisation does not have any impacted units left in inventory
4. Contact your local BD representative to discuss the availability of product alternatives.
5. Return the completed customer response form to <<insert contact details here>> for **as soon as possible or no later than 17th June 2021.**
   - **NOTE:** If you no longer 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,

Prof. Dr. Klaus Hoerauf,
Vice President Medical Affairs,
EMEA Region

Lorna Darrock
Senior Manager, Post Market Quality
BDX EMEA

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Customer Response Form – MDS-21-4111

BD Venflon Pro™ IV Cannula

REF & Lot Number: See Appendix 1

Please read in conjunction with Field Safety Notice MDS-21-4111 and return completed and signed form as soon as possible or **no later than 17th June 2021** to <*<insert fax/email address here>>*.

- **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 in our possession.

OR

☐ We have the following units of the affected product in our possession and I confirm that the units have been destroyed *(Please complete the table below with the lot number and the number of units destroyed)*

Catalogue Number (REF)	Lot Number	Quantity Destroyed (units)		Catalogue Number (REF)	Lot Number	Quantity Destroyed (units)

Account/Organisation Name:	
Department *(if applicable)*:	
Address:	
Postcode:	**City:**
Contact Name:	
Job Title:	
Contact Telephone Number:	**Contact E-mail Address:**
Signature:	**Date:**

This form must be returned to BD before this action can be considered closed for your account.

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Appendix 1: Impacted Catalogue Numbers (REF) & example of Labelling

BD has an on-line tool to support the identification of impacted lot numbers located at: http://www.bd.com/MDS-21-4111.

Catalogue Number (REF)	Product Name
393210	VENFLON PRO 14GA 2.0MM OD 45MM L
393209	VENFLON PRO 16GA 1.8MM OD 45MM L
393208	VENFLON PRO 17GA 1.5MM OD 45MM L
393207	VENFLON PRO 18GA 1.3MM OD 45MM L
393206	VENFLON PRO 18GA 1.3MM OD 32MM L
393204	VENFLON PRO 20GA 1.1MM OD 32MM L
393202	VENFLON PRO 22GA 0.9MM OD 25MM L

Location & identification of EtO Sterilisation Symbol on Shelf Labelling (Representative)