1030 Eskdale Road
Winnersh Triangle
Wokingham
RG41 5TS
www.BD.com

1st March 2021

URGENT: FIELD SAFETY NOTICE – MDS-20-3801

BD Venflon™ Pro Safety (VPS) Needle Protected I.V. Cannula
REF: See Attachment 1

Type of Action: Advisory

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your immediate attention.

Dear Customer,

BD is issuing an advisory Field Safety Notice for lots of BD Venflon™ Pro Safety (VPS) Needle Protected I.V. Cannula which have been sterilized by Ethylene Oxide (EtO). According to our distribution records your organization may have received the impacted product.

Description of the Problem

BD has confirmed an increase in reports for leakage from the injection port of the BD Venflon™ Pro Safety (VPS) Needle Protected I.V. Cannula (Figure 1) to 2.5 complaints per million devices sold when sterilized by ETO (Figure 2). The identified root cause is due to a modification in the injection port valve dimensions in June 2019 to accommodate EtO sterilisation. This issue is seen primarily on the 14-18G devices with lower occurrences on alternative gauge devices.

Figure 1: Image of BD Venflon™ Pro Safety (VPS) Needle Protected I.V. Cannula

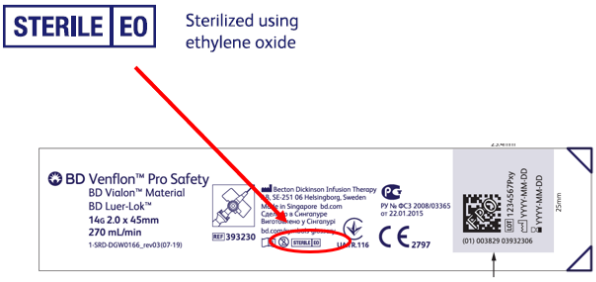

Figure 2: Representative image of product labelling indicating method of EtO sterilisation

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.
Any failures to date have not resulted in any reported serious patient harm. No specific patient follow-up activities are required if the product has already been safely used.

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Advice for Clinical Users

BD would like the users of the BD Venflon™ Pro Safety (VPS) Needle Protected I.V. Cannula to be aware of this potential issue and maintain an increased level of vigilance while **using these devices which have been EtO sterilized.** The method of sterilization can be identified on the product label (refer to Figure 2 and Attachment 1).

1. If possible, do not use the injection port in critical situations or where the visibility of the device can not be maintained throughout the procedure.

2. Alternatively, consider placing a second IV catheter or use an alternate delivery device or route such as an extension set or 3 way stopcock per your clinical judgement based on patient condition and use case.

3. If you need to use the injection port:
    - When the catheter is inserted in the patient, keep the entire device visible and monitor it for any leakage of blood or fluids from the injection port.
    - Pay particular attention for any leakage after any administration of fluids or medication through the injection port.

There is no requirement for customers to return any BD Venflon™ Pro Safety (VPS) Needle Protected I.V. Cannula. These products can continue to be used in accordance with the guidance in this safety notice.

Corrective Actions by BD

BD has revised and implemented corrective actions to the port valve and future product will be sterilized by radiation (E-beam), which will be denoted by the following symbol on the packaging:

This was the previous sterilization method utilized for BD Venflon™ Pro Safety (VPS) Needle Protected I.V. Cannula prior to June 2019.

Actions for Customers to take:

1. Circulate this Field Safety Notice to all those within your organisation that may use the BD Venflon™ Pro Safety (VPS) Needle Protected I.V. Cannula

2. If you have further distributed the product, please identify those users and notify them at once of this advisory.

3. Complete the customer response form on page 4 and return it to BDUKFieldAction@bd.com **as soon as possible or no later than 31st March 2021.** If you no longer use the product, it is still important that you return the Customer Response Form for our reconciliation purposes.

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Contact Reference Person

If you have any questions about this, please contact BDUKFieldAction@bd.com.

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, EMEA

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Customer Response Form - MDS-20-3801
BD Venflon™ Pro Safety (VPS) Needle Protected I.V. Cannula

REF: See Attachment 1

Please read in conjunction with Field Safety Notice MDS-20-3801 and return the completed and signed form as soon as possible or **no later than the 31st March 2021** to BDUKFieldAction@bd.com.

By signing below, you confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Name of Trust / Organisation			
Your Facility Address			
Postcode			
Telephone number		**E-mail address**	
Name of your supplier for this product *(if not direct from BD)*			

	Facility / Hospital Name	**Postcode**
Please list all Facilities / Hospitals covered by your response *(e.g. other hospitals within your Trust)*		

Your Name		**Job Title**	
Signature		**Date**	

This form must be returned to BD before this action can be considered closed for your account. Please return your completed and signed Response Form to BDUKFieldAction@bd.com.

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

Catalogue Number (REF)	Product Name
393222	Venflon Pro Safety 22GA 0.9 mm x 25 mm
393224	Venflon Pro Safety 20GA 1.1 mm x 32 mm
393226	Venflon Pro Safety 18GA 1.3 mm x 32 mm
393227	Venflon Pro Safety 18GA 1.3 mm x 45 mm
393228	Venflon Pro Safety 17GA 1.5 mm x 45 mm
393229	Venflon Pro Safety 16GA 1.8 mm x 45 mm
393230	Venflon Pro Safety 14GA 2.0 mm x 45 mm
393280	Venflon Pro Safety 22GA 0.9 mm x 25 mm INSTAFLASH
393281	Venflon Pro Safety 20GA 1.1 mm x 32mm INSTAFLASH
393282	Venflon Pro Safety 18GA 1.3 mm x 32mm INSTAFLASH
393283	Venflon Pro Safety 18GA 1.3 mm x 45mm INSTAFLASH

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