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

29th July 2021

URGENT: FIELD SAFETY NOTICE – MDS-21-4144

BD SmartSite™ Needle Free Valve

REF & Lot Numbers: See Appendix 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 specific lots of BD SmartSite™ Needle Free Valve products, as listed in Appendix 1, and according to our distribution records your organisation may have received the impacted product, which was shipped from 23rd January 2020.

Description of the Problem

Based on customer feedback, BD has identified potential issues with the valve of the Needle-free Connector for the products listed in Appendix 1 resulting in difficulty to flush, flow issues, and partial or total occlusions on the Extension Sets with SmartSite™ and Standalone SmartSite™ connectors. Only the lot numbers listed in Appendix 1 are affected by this issue.

BD has an online tool to support the identification of impacted lot numbers: https://www.bd.com/MDS-21-4144.

Clinical Impact

The health consequences associated with the use of an occluded connector is a delay in therapy that can potentially lead to an injury that requires medical intervention.

BD has not identified any reports of serious adverse events to date that could be associated with this Field Safety Corrective Action. No specific patient follow-up activities are required if the product has already been used or already safely connected to the female luer of connecting device.

Advice for Clinical Users

As a result of this feedback and to mitigate the occurrence of the connector occluding, BD is recommending the following steps be followed prior to clinical use of the needle-free connector

- Depress the syringe plunger whilst the syringe is still attached to the needle-free connector.
- If unable to depress the plunger, pull back on the syringe plunger and depress the syringe plunger again. Repeating this step may assist in opening the needle-free connector valve.

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- If the valve still is not open; without disconnecting the syringe male luer tip from the BD SmartSite™ valve surface, carefully unthread and rethread the syringe to partially disengage and reengage the syringe.
- Repeating this step up to three times may assist in opening the needle-free valve.

  Note: To maintain sterility, do not allow the syringe and needle-free valve to completely disconnect
- If previous steps do not open the valve, then replace with another BD SmartSite needle-free connector.
- After the steps above, proceed with the existing instructions for use for product.

Actions by BD:

1. BD has identified the root cause and initiated corrective actions to prevent recurrence of this issue.

Actions for Customers to take:

1. Circulate this Field Safety Notice to all those within your organisation that may use the BD SmartSite™ Needle Free Valve devices listed in Appendix 1.

2. Where a potential delay in therapy cannot be clinically tolerated (e.g., in an emergency situation) consideration should be given to administering the critical drug directly into the catheter hub or through a different route.

3. If you have further distributed the product, please identify those users and notify them at once of this Field Safety Notice.

4. If you continue to experience issues with the BD SmartSite™ Needle Free Valve report as a complaint to BD per your normal process.

5. Complete the customer response form on page 4 and return it to compliance@hc21.group **as soon as possible or no later than 31st August 2021.** If you no longer use the product, it is still important that you return the Customer Response Form for our reconciliation purposes.

There is no requirement for customers to return any BD SmartSite™ Needle Free Valve devices to BD. These products can continue to be used in accordance with the guidance in this safety notice.

Contact Reference Person

If you have any questions about this, please contact your local Healthcare 21 Group representative.

We confirm that the appropriate regulatory agencies have been informed of these actions.

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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

Senior Manager, Post Market Quality, EMEA

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Customer Response Form – MDS-21-4144

BD SmartSite™ Needle Free Valve

REF & Lot Numbers: See Appendix 1

Please read in conjunction with Field Safety Notice MDS-21-4144 and return the completed and signed form as soon as possible or **no later than 31st August 2021** to compliance@hc21.group.

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 sites within your Trust / organisation.)*		

**Please note you may still receive reminder notifications if you cover multiple impacted sites but do not declare these above.*

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

This form must be returned to compliance@hc21.group before this action can be considered closed for your account.