



5th January 2022

UPDATED

URGENT: FIELD SAFETY NOTICE – MDS-21-4144

BD SmartSite™ Needle Free Valve

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,

On August 2nd, 2021, BD issued an Advisory Field Safety Notice to customers of the specific lots of BD SmartSite™ Needle Free Valve products, as listed in Appendix 1.

The advisory notice provided additional instructions for Users to follow prior to clinical use of the needle-free connector to mitigate the occurrence of the connector occluding, following customer feedback.

After a review and further discussions with the BfArM, both parties have agreed to update this action from an “advisory” to a “product recall” for any remaining product inventory.

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. The risk associated with the defect has not increased since the previous Field Safety Notice and BD has not received any product complaints from the German market associated with this issue.

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.

Actions by BD:

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



Actions for Customers to take:

1. Identify, quarantine, and destroy any of the impacted lots left in your inventory.
2. Circulate this Field Safety Notice to all those within your organisation that may use the BD SmartSite™ Needle Free Valve.
3. If you have further distributed the device/s, please identify those users, and notify them at once of this updated Field Safety Notice.
4. Complete the customer response form on page 4 and return it to <<insert contact details here>> **as soon as possible or no later than 7th February 2022**. If you no longer use the product, it is still important that you return the Customer Response Form for our reconciliation purposes.

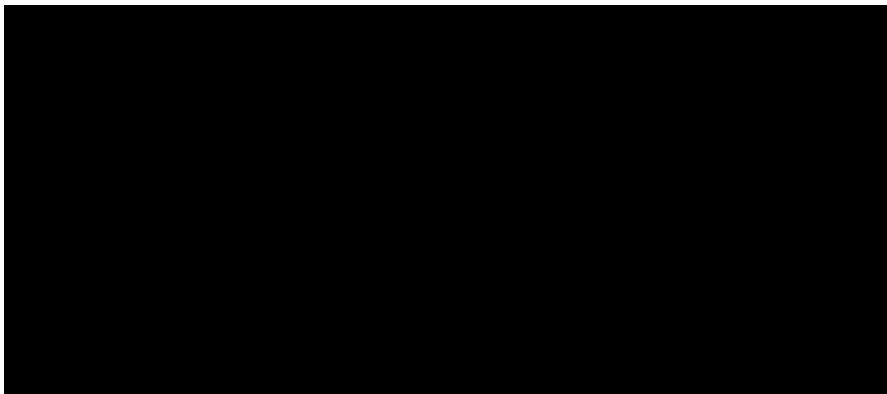
Contact Reference Person

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,





UPDATED Customer Response Form – MDS-21-4144
BD SmartSite™ Needle Free Valve

Please read in conjunction with the Field Safety Notice MDS-21-4144 and return the completed and signed form as soon as possible or **no later than 7th February 2022** to **<<insert contact details>>**.

By signing below, you 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 units of the affected product and confirm that the following numbers of units have been destroyed & replacement product will be provided (*Please note there may be delays in the replacement product subject to product availability*).

REF	Lot Number	Quantity Destroyed	REF	Lot Number	Quantity Destroyed

Table 1: Impacted Lot Numbers & Expiry Dates

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.