

27th February 2024

URGENT: FIELD SAFETY NOTICE – MMS-24-4958

BD BodyGuard™ MicroSets

REF: Refer to Table 1 **Lot Numbers:** All unexpired lots (refer to Appendix 1)

Type of Action: Product Removal

Attention: Clinical Personnel, Medical & Nursing Managers, Risk Managers, Biomedical Personnel, Purchasing/Warehouse Managers

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

Dear Customer,

BD is conducting a Field Safety Corrective Action to remove all unexpired lots of **BD BodyGuard™ MicroSets**, listed in Table 1. According to our distribution records your organisation may have received the impacted product. Product was distributed between 8th July 2021 and 17th January 2024.

Manufacturer’s SRN: IL-MF-000030321

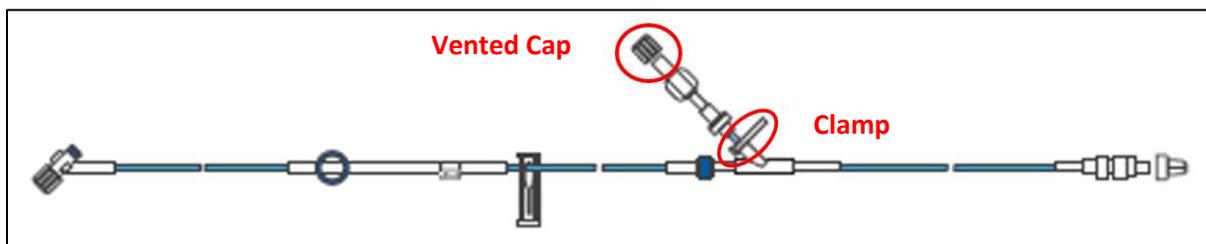
Product Code (REF)	Lot Number	Expiry Date	UDI
100-184XSYK	All unexpired lots Refer to Appendix 1	Refer to Appendix 1	Refer to Appendix 1
120-160XCSEK			
120-160XCSK			

Table 1: Impacted product

This product removal is limited to all unexpired product codes listed in Table 1.

Description of the problem

Based on customer feedback, BD has identified that the **BD BodyGuard™ MicroSets**, listed in Table 1, have the potential for the Y-port clamp to loosen unintentionally during clinical use which could permit air to ingress to the line through its vented cap (see Picture 1).



Picture 1: Location of clamp and vented cap on the Y-port



Clinical risk

The severity of harm with infusion of air is dependent on the amount of air infused, the speed of the infusion and the physiological conditions of the patient. In a worst-case scenario, air entering the infusion line could result in severe adverse health consequences, such as stroke, life threatening illness or death. This risk of air ingress through the Y-port is mitigated if it has an infusion line or other air-tight device (e.g. un-vented cap) connected.

To date, BD has received six (6) complaints globally, representing a complaint rate of 0.003%, that are potentially associated with this issue, and, of these, there have been two (2) potential adverse events, representing a reported adverse event rate of 0.001%.

Actions for Clinical Users:

- Cease use of the specific BD BodyGuard™ MicroSets listed in Table 1 and seek alternate product.
- Refer to Appendix 2 for a list of recommended alternates.
 - *If a 2nd access port is required, please contact your local BD representative to discuss available connectors from the BD portfolio.*
- For impacted devices currently in use, BD instructs that an infusion line or other air-tight device (e.g. un-vented cap) be connected to the Y-port of the BD BodyGuard™ MicroSet for the duration of the current infusion therapy. Otherwise, immediately replace with an alternate product, per Appendix 2.
- No additional follow-up activities required for patients that have completed therapies.

BD Actions:

BD has ceased distribution of the product listed in Table 1 until actions are implemented to correct the issue.

BD is investigating the root cause and will take corrective actions to prevent recurrence of this issue.

Customer Actions:

- Cease use of any unused affected **BD BodyGuard™ MicroSets**.
- Identify and quarantine all unused affected **BD BodyGuard™ MicroSets**.
- Make a note of the lot numbers and destroy all unused affected units.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 22nd March 2024**.
- Circulate this notice to all those who need to be aware within your organisation or to any organization where the potentially affected products have been transferred.
- If you experience any issues, please report as a complaint as per your normal process.

Distributor Actions:

- Cease distribution.
- Identify, quarantine, making a note of the lot numbers then destroy all unused affected **BD BodyGuard™ MicroSets**.



- Identify the facilities where you have distributed affected product and notify them immediately of this notice.
 - Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes by **22nd March 2024**.
- Complete and return the Customer Response Form following completion of your reconciliation activities.
- If you experience any issues, please report as a complaint as per your normal process.

	End User with Inventory	End User with ZERO inventory	Where to send completed form
Purchased directly from BD	Complete the form in its entirety Upon receipt, BD will process the response, and you will receive credit for unused product.	Complete form and check the box indicating “no inventory”	BDUKFieldAction@bd.com
Purchased from a Rockford Healthcare	Complete all fields on the form and contact your distributor to arrange for credit .	Complete form and check the box indicating “no inventory”	fieldsafetyaction@rockford.ie

Contact reference person

If you have any questions about this, please contact Rockford Healthcare at +353 1 450 9050, or email fieldsafetyaction@rockford.ie.

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
Associate Director, Post Market Quality
EMEA Quality



Customer Response Form – MMS-24-4958

BD BodyGuard™ MicroSets

REF: Table 1 **Lot Numbers:** All unexpired lots (refer to Appendix 1)

Return to fieldsafetyaction@rockford.ie as soon as possible, or **no later than the 22nd March 2024.**

- I confirm this Field Safety 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 facility. Affected product has been used.

All product that is not available for destruction will be considered as dispositioned at your location and therefore physically unavailable unless otherwise specified.

OR

We have the following units of the affected product as listed in **Appendix1** 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, continue on separate sheet if required. Credit will only be sent on completion & return of this form).*

REF:	Lot Number/s:	Units destroyed <i>(insert quantity below)</i>

Account/Organisation Name:	
Department <i>(if applicable):</i>	
Address:	
Postcode:	City:
Contact Name:	
Job Title:	
Contact Telephone Number:	Contact E-mail Address:
Name of your supplier for this product <i>(if not direct from BD)</i>	
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.*



Appendix 1: List of Product Information

Catalog No. (REF)	Lot Number	UDI-DI	Expiration Date
100-184XSYK	13059278	(01)00885403480112(17)240704(10)13059278	31-Jul-2024
100-184XSYK	13139369	(01)00885403480112(17)251210(10)13139369	31-Dec-2025
100-184XSYK	13211420	(01)00885403480112(17)261002(10)13211420	02-Oct-2026
120-160XCSEK	13060123	(01)00885403478911(17)240619(10)13060123	30-Jun-2024
120-160XCSEK	13070007	(01)00885403478911(17)240720(10)13070007	31-Jul-2024
120-160XCSEK	13074347	(01)00885403478911(17)240801(10) 13074347	30-Aug-2024
120-160XCSEK	13074348	(01)00885403478911(17)240803(10) 13074348	31-Aug-2024
120-160XCSEK	13113533	(01)00885403478911(17)250528(10) 13113533	31-May-2025
120-160XCSEK	13139407	(01)00885403478911(17)250606(10) 13139407	30-Jun-2025
120-160XCSEK	13141218	(01)00885403478911(17)250621(10) 13141218	30-Jun-2025
120-160XCSEK	13147538	(01)00885403478911(17)250716(10) 13147538	31-Jul-2025
120-160XCSEK	13150164	(01)00885403478911(17)250718(10) 13150164	31-Jul-2025
120-160XCSEK	13163586	(01)00885403478911(17)251112(10) 13163586	30-Nov-2025
120-160XCSEK	13169751	(01)00885403478911(17)251113(10) 13169751	30-Nov-2025
120-160XCSEK	13172478	(01)00885403478911(17)251119(10) 13172478	19-Nov-2025
120-160XCSEK	13199882	(01)00885403478911(17)260306(10) 13199882	06-Mar-2026
120-160XCSEK	13210795	(01)00885403478911(17)260401(10) 13210795	30-Apr-2025
120-160XCSK	13004757	(01)00885403445616(17)240330(10)13004757	31-Mar-2024
120-160XCSK	13028606	(01)00885403445616(17)240324(10)13028606	31-Mar-2024
120-160XCSK	13028607	(01)00885403445616(17)240328(10)13028607	31-Mar-2024
120-160XCSK	13068123	(01)00885403445616(17)240731(10)13068123	31-Jul-2024
120-160XCSK	13074360	(01)00885403445616(17)240801(10) 13074360	31-Aug-2024
120-160XCSK	13106218	(01)00885403445616(17)241227(10) 13106218	31-Dec-2024
120-160XCSK	13107829	(01)00885403445616(17)250123(10) 13107829	31-Jan-2025
120-160XCSK	13107831	(01)00885403445616(17)250117(10) 13107831	31-Jan-2025
120-160XCSK	13113534	(01)00885403445616(17)250205(10) 13113534	28-Feb-2025
120-160XCSK	13117140	(01)00885403445616(17)250207(10) 13117140	28-Feb-2025
120-160XCSK	13135964	(01)00885403445616(17)250231(10) 13135964	31-Jul-2025
120-160XCSK	13138520	(01)00885403445616(17)250728(10) 13138520	31-Jul-2025
120-160XCSK	13150344	(01)00885403445616(17)250803(10) 13150344	31-Aug-2025
120-160XCSK	13150345	(01)00885403445616(17)251120(10) 13150345	30-Nov-2025
120-160XCSK	13150346	(01)00885403445616(17)251127(17)13150346	27-Nov-2025
120-160XCSK	13150347	(01)00885403445616(17) 251129(10)13150347	22-Nov-2025
120-160XCSK	13163587	(01)00885403445616(17) 251208(10) 13163587	31-Dec-2025
120-160XCSK	13171780	(01)00885403445616(17)251210(10) 13171780	31-Dec-2025
120-160XCSK	13171781	(01)00885403445616(17) 260122(10) 13171781	31-Jan-2026
120-160XCSK	13178410	(01)00885403445616(17)260123(10) 13178410	31-Jan-2026
120-160XCSK	13185457	(01)00885403445616(17)260418(10) 13185457	24-Apr-2026
120-160XCSK	13185458	(01)00885403445616(17)260417(10) 13185458	30-Apr-2026
120-160XCSK	13185459	(01)00885403445616(17)260417(10) 13185459	26-Apr-2026
120-160XCSK	13192934	(01)00885403445616(17)260422(10) 13192934	30-Apr-2026
120-160XCSK	13206716	(01)00885403445616(17)260417(10) 13206716	30-Apr-2026

Appendix 2: List of Recommended Alternate BD Products

Impacted Product		Recommended Alternate Product	
<p>100-184XSYK BD BodyGuard™ MicroSet Blue Microbore Tubing, Syringe Adapter, Y Port, Female Luer Connector, Anti-Siphon Valve, Male Luer Connector</p>		<p>100-184XSK BD BodyGuard™ MicroSet Blue Microbore Tubing, Syringe Adapter, Anti-Siphon Valve, Male Luer Connector</p>	
<p>120-160XCSEK BD BodyGuard™ MicroSet Blue Striped Microbore Tubing, Spike, Y Port, Female Luer Connector, Anti-Siphon Valve, Male Luer Connector</p>		<p>PCA00001 BD BodyGuard™ MicroSet Blue Striped Microbore Tubing, Spike, Anti Siphon Valve, Male Luer Connector.</p>	
<p>120-160XCSK BD BodyGuard™ MicroSet Blue Striped Microbore Tubing, Spike, Y Port, Female Luer Connector, Anti-Siphon Valve, Male Luer Connector</p>			