National Procurement

NHS National Services Scotland

CUSTOMER ALERT/PRODUCT CHANGE NOTIFICATION					
NP Reference:	CAN457	Supplier/MHRA Ref:	BD Field Safety Notice MMS-23-4678 dated February 9th, 2023	Version:	1
Issue Date:	14/2/2023	Issued By:	Arthur McCart	Close Date:	14/2/2023
FAO (NHS Boards)	NHS Tayside, Fife, Lothian, GGC, D&G, Ayrshire & Arran				

A Field Safety Notice has been issued by: National Procurement ☐ Supplier ☒

Section 1: Details of the Supplier/Product	
Product Description	BD BodyGuard™ MicroSet Yellow Striped Microbore Tubing, 90° Spike, Anti Siphon Valve, Male Luer Connector
Supplier	BD
Supplier Product code	100-163XE90SK
NDC SKU's	**202560**
Lot #	Refer to BD FSN for full list of affected products
NP Contract Ref	NP146/18

Description of the Issue
The National Distribution Service (NDS) has received a Field Safety Notice (FSN) from BD concerning **BD BodyGuard™ MicroSets**. This advisory is limited to the product codes listed in Appendix 1 of the FSN, no other product codes are affected.

One of the items listed, code 100-163XE90SK, is supplied from the NDS.

BD has identified internally through a product review that the **BD BodyGuard™ MicroSets** do not currently have the evidence to support compliance with Ethylene Oxide residual level requirements (per ISO 10993-7:2008/AMD. 1:2019) for use in special populations, specifically children, infants, neonates and pre-mature neonates.

Therefore, these devices are currently being limited for use with adults until the compliance evidence is gathered. BD is gathering the evidence to support the use in the entire patient population.

Clinical risk
BD does not have any data to suggest that the lack of compliance evidence has resulted in any clinical harm but, in the worst case, if the EO residual levels are too high for these intended special patient populations (children, infants, neonates and pre-mature neonates), there may be an elevated risk of health consequences. If the devices have already been safely used no additional follow-up activities are required.
To date there has been no adverse events worldwide related to this issue.

There is no requirement for customers to return any BD BodyGuard™ MicroSets to BD. These products can continue to be used in accordance with the guidance in this safety notice.

Advice for Clinical Users:
Do not use the BD BodyGuard™ MicroSets with special populations, specifically children, infants, neonates and pre-mature neonates. For devices *in situ* with children, infants, neonates and pre-mature neonates BD instructs to immediately cease use and an alternate treatment or device be sourced.

Please refer to the BD FSN communication sent with this NDS Customer Alert Notice.

Section 2: Actions to be taken by NHS Boards

- This NDC notice **CAN457** and the **BD Field Safety Notice** dated 9th February 2023 must be shared with users and all those who need to be aware within your organisation.
- Review the information in **Appendix 1** to determine if **BD BodyGuard™ MicroSets** in your possession are impacted by this advisory.
- Complete and return the **Customer Response Form** (page 4 of FSN) even if you no longer have any inventory remaining in your facility by **8th March 2023**.
- Circulate this notification to all those who need to be aware within your organisation
- If you experience any issues with the **BD BodyGuard™ MicroSets**, please report as a complaint as per your normal process.
- If you have any questions about this, please contact BD at BDUKFieldAction@bd.com

PLEASE DO NOT RETURN STOCK TO THE NDC unless authorised by the NDC Quality Manager

Regards, **Quality Team**
Tel 01698 79 4488
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