MHRA Device Safety Information

Reference: MDSI2304 **Issued:** 21 February 2023 **Review Date:** 21 February 2024

BD BodyGuard MicroSets and residual ethylene oxide: devices may continue to be used to treat paediatric patients 5kg and above

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 20 February 2023. The original webpage can be accessed here.

Summary

As a precautionary measure, following an MHRA assessment of currently available data on EO levels, alternative devices to the BD BodyGuard Microsets should be sought in users of 5kg bodyweight and below.

Action for health care professionals and carers

- Stop using BD BodyGuard™ Microsets in patients below 5kg. Note that they may continue to be used in patients 5kg and above.
- Consider the need of additional training on alterative devices where required.

Equipment details

Device Name: BD BodyGuard™ MicroSets

Affected lot numbers: All

Manufactured by Becton, Dickinson (BD)

Background

Ethylene oxide (EO) is a gas commonly used for sterilisation of different types of medical devices. The sterilisation process consists of a number of highly controlled and monitored stages, including the removal of ethylene oxide after treatment. The amount of residual EO that is allowed has been set by the international standard ISO 10993-7:2008 according to contact time of the medical device with the person. These allowable limits were selected to ensure that any residual levels present on the medical device after sterilisation pose minimal risk. EO is a volatile chemical and following sterilisation the presence of EO further decreases over time.

Levels of residual EO considered safe for adult patients are laid out in ISO 10993-7:2008 which BD Bodyguard™ Microsets meet. These guidelines were amended in 2019 (ISO 10993-7:2008/AMD. 1:2019) to adjust allowable limits for neonates and infants according to the appropriate body mass calculations; this amendment did not apply when these devices were brought to market and BD do not currently hold evidence to demonstrate an evaluation of the residual EO levels in line with these amended limits. The MHRA has been working closely with the manufacturer and the information available to date indicates that there are no new safety concerns associated with the use of these devices.

The FSN MMS-23-4678 issued by BD is the result of an amendment to the international standard which sets outs the applicability of allowable limits of ethylene oxide (EO) for neonates and infants on medical devices. The MHRA is not aware of any specific safety concerns with regards to the

use of these devices. The manufacturer is currently working to assess whether the residual levels of EO are in line with amended limits for low weight children.

As precautionary measure, following MHRA assessment of currently available data on EO levels, alternative devices to the BD BodyGuard™ Microsets should be sought in users of 5kg bodyweight and below.

Suggested onward distribution

Ambulance Services
Emergency Department
Health & Safety
Intensive Therapy Units
Medical Admissions
Nursing
Paediatrics
Risk Management
Supplies/procurement
Surgical

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

Accessibility: Please contact us using the above details if you are blind or have a sight impairment and would like to request this alert in a more suitable format.

IRIC remit: general information about adverse incidents, safety alerts and IRIC's role can be found in CEL 43 (2009), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities,* issued 30 October 2009.

Report an incident: Information on how to report an adverse incident

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