Medicines & Healthcare products Regulatory Agency

Device Safety Information (DSI)

BD BodyGuard MicroSets and residual ethylene oxide: devices may continue to be used to treat paediatric patients 5kg and above; DSI/2023/004

Devices Details

BD BodyGuard™ MicroSets
Affected lot numbers: all lots
Manufactured by Becton, Dickinson (BD)

Summary

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 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.

Introduction

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.

As a precautionary measure, alternative devices should be sought for users under 5kg bodyweight.

Actions

Actions for health care professionals and carers

- BD BodyGuard Microsets may continue to be used in patients 5kg and above
- Consider the need of additional training on alterative devices where required

Actions for patients

- This DSI is intended for healthcare professionals and carers. If you have any concerns about this advice, please contact the specialist team with responsibility for your care for assistance.