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To:
- Trust and ICB:
  - Medical directors
  - Clinical directors
  - Chief pharmacists
  - EPRR leads
- NHS England regional:
  - Directors
  - Medical directors
  - Directors of specialised commissioning
  - Medical directors of specialised commissioning

NHS England
Wellington House
133-155 Waterloo Road
London
SE1 8UG

**21 February 2023**

Dear colleagues,

## BD BodyGuard™ MicroSets

We are writing to draw your attention to a Field Safety Notice (FSN) issued by Becton Dickinson (BD) for the **BD BodyGuard™ MicroSets** on Thursday 9 February 2023 and related MHRA Device Safety Information (DSI) published on 20 February 2023. This letter sets out what action clinicians and homecare companies need to take as a result.

The FSN affects a device used to administer home parenteral nutrition, enzyme replacement therapy, and in-hospital pain management to paediatric patients.

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 (as per ISO 10993-7:2008/AMD. 1:2019) for use in special populations, specifically children, infants, neonates and pre-mature neonates.

The DSI confirms that as a precautionary measure, alternative devices to the **BD BodyGuard™ MicroSets** should be sought for patients below 5kg bodyweight. Clinicians and homecare companies are therefore asked to work together to identify any patients in this category who currently use these devices. These patients should be switched to alternative giving sets, which will result in them being issued an alternative pump. Clinicians and homecare companies are reminded that the Homecare Framework stipulates that pumps in Band A should be prescribed as a first line. NHS England has assessed that there are sufficient pumps and giving sets to enable these switches to be made.

Homecare companies are asked to support patients, their parents and carers with appropriate training to use the new equipment.

No action is needed for equipment used by patients 5kg or above (both paediatric and adult).

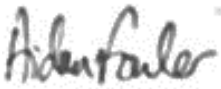
Further background information can be found in the FSN and DSI. If you have any further queries about this issue please contact BD directly on 0800 917 8776 or BDUKFieldAction@bd.com

**Information for parents and carers of patients below 5kgs**

The following key messages may be helpful when discussing the switching of devices with parents and carers.

- As a precautionary measure the pumps and tubes which deliver your child's nutrition support/medication are being withdrawn whilst the manufacturer carries out additional checks to make sure the devices fully comply with the latest regulations on quality and safety.
- This means the pump and tubes your child uses will be switched to another make or model.
- There is no evidence that the pump or tubes you have been using has caused or will cause your child any harm. This is purely a precaution whilst the manufacturer completes its checks.
- There are a number of pump models available, and your clinician and the homecare company will work with you to determine the one that best suits you and your child's needs.
- Homecare companies will determine whether any other equipment needs switching to ensure compatibility with replaced devices.
- Clinicians and homecare companies are working to ensure that families of all patients that have switched equipment are fully familiar with the new models and will be on hand to resolve any queries and offer training.
- The prescription for your child's nutrition support or other drugs will not change – this relates only to the equipment used to deliver it into the body.
- When issued with new equipment, the old pump, and any unused stock should be returned to your homecare provider.

Yours sincerely,



**Dr Aidan Fowler**
National Director of Patient Safety in England,
NHS England

**Prof. James Palmer**
National Medical Director, Specialised Services, NHS England