National Patient Safety Alert

MHRA

Supply disruption of sterile infusion sets and connectors manufactured by Becton Dickinson (BD)

Date of Issue:	11-Mar-21	Reference No:	NatPSA/2021/001/MHRA

This alert is for action by: primary and secondary care, blood transfusion services, specialist outpatient settings, oncology providers, hospices, private healthcare

This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by a senior member of staff e.g. Medical Director supported by Chief Pharmacist, Chief Nurse, Head of Infection Control and Head of Procurement/Supplies or equivalent roles.

Explanation of identified safety issue:

Becton Dickinson (BD) have notified MHRA that the sterility of some of their devices cannot be guaranteed due to quality issues with their third-party sterilisation provider. BD is recalling all affected stock of the following products:

- Infusion sets for specific Alaris pumps
- Gravity infusion sets and connectors

Although the devices are likely to be sterile this cannot be guaranteed so there is a very small risk of infection from treatment with these devices. There will be supply disruption whilst BD transfer products to a new sterilisation provider.

Affected product codes are listed in the Field Safety Notice (FSN).

The quality issue was recently identified but ongoing for a number of years. No infection issues have been identified relating to these products.

Supply disruption is to be expected for 4 weeks. Mutual aid of alternative infusion devices and associated consumables is advised to ensure that clinical risk is minimised.

The risks of rapidly changing clinical practice or using unfamiliar devices must be balanced against the risk of continuing to use these products while they remain available.

Unusual or low-virulence organisms isolated from blood culture, which are commonly considered contaminants, should be considered potentially pathogenic in discussion with the local infection specialist.

Based on current evidence, there is no need for a review of patients previously treated with these devices.

Actions required

NOTE:
Do not disconnect patients from already running infusions unless an alternative means of delivery has been identified and is available.

Actions to be complete by 31 March 2021

1. Immediately identify whether your organisation uses any of the following Alaris models of pumps:
   - CC
   - GP
   - VP
   - GW/GW800
   - SE
   - IVAC 590 series

2. Use alternative pumps and giving sets or alternatives to intravenous infusion where they are available, and it is safe to do so.

3. Train staff and verify competency before using alternative pumps and ensure training records are updated.

4. Once alternatives are available, remove unused Alaris pump giving sets, gravity infusion sets and connectors from shelves and storage areas and quarantine these devices for later analysis if indicated.

5. If no alternative devices or clinical approaches are available you should:
a) Undertake and document a risk assessment.
b) Follow established local protocols for resource shortage escalation or contingency.
c) Set up systems to ensure that any infections that may be linked to these infusion sets are reported, as appropriate, in your region.

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Additional information:

A review of data held by the MHRA showed no reports of infections in last 10 years associated with BD pumps/infusion sets. There are a small number of incidents reported about all infusion sets in the same 10-year period. The manufacturer has not had any reports of infections related to these devices. Manufacturing of the affected devices is conducted in an ISO accredited cleanroom facility; the sterilisation processes will have achieved a reduction in contamination. The devices are likely to be sterile, but with a lower sterility assurance level than is the standard.

BD have identified that the following sets are affected as part of the scope of this issue, as detailed in their FSN.

Gravity IV sets and connectors		
Product	**Purpose**	**Alternative**
Primary and secondary administration sets	IV fluids and drug administration	Other non-dedicated IV sets from BD or competitor portfolio
Transfusion sets	Blood transfusions	Other transfusion sets from BD or competitor portfolio
Multi-way oncology sets	Oncology drug infusion delivery	Other oncology sets from BD or competitor portfolio
SmartSite Needle-free connector	Needleless connector to enable catheter access to infusion	Other connector technology from BD or competitor portfolio
Vial and bag access devices	Needleless bag and vial access, including hazardous drug protection	Needle/syringe access

Infusion sets for Alaris pumps		
Product	**Purpose**	**Alternative**
Large volume infusion pump sets	Accurate IV infusion and transfusion delivery in general wards, OR and ICU	No alternative sets – see clinical advice in FSN
Syringe pump sets with in-line pressure monitoring	Accurate IV infusion and transfusion delivery in general wards, OR and ICU	No alternative sets – see clinical advice in FSN

Stakeholder engagement

Department of Health & Social Care
Devolved Administrations
NHS Supply chain / procurement
Public Health England
NHS Blood & Transplant
CQC

You can report any suspected or actual adverse incidents involving these devices through your healthcare institution's local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales.

Department of Health www.health-ni.gov.uk
NHS National Services Scotland
Llywodraeth Cymru Welsh Government
NHS