MHRA Device Safety Information

MDSI2108 30 June 2021

Medical devices sterilised by Steril Milano - potential for incomplete sterilisation

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 29 Jun 2021. The original webpage can be accessed here.

Summary

Fraudulent activity by this third-party sterilisation provider has been identified. Multiple medical device manufacturers are affected. Manufacturers are advising customers of actions required to mitigate risks.

Background

Steril Milano is a third-party supplier of sterilisation services to manufacturers of medical devices. It is based in Italy. Fraudulent activities by the company became apparent in early 2021 after it was bought by a new parent company, Ionisos. Once the fraudulent activities were uncovered, the certification for the sterilisation plant was withdrawn, meaning it could no longer provide sterilisation services.

The scale of the problem is limited to products which had already been sterilised when the certification was withdrawn on 14 April 2021. For devices processed before this date, a sterilisation process had been carried out and the devices are likely to be sterile, but they may not have been sterilised in line with the documented, validated process. However, for the majority of devices the risk to patients is low. The MHRA is not aware of adverse incidents which can be linked back to Steril Milano.

The MHRA was advised of 88 medical device manufacturers for whom Steril Milano provided sterilisation services. Additional companies, that are part of the supply chain for the affected manufacturers, have also been identified.

What the MHRA has done

To assess and mitigate the risk of further incidents, the MHRA proactively contacted manufacturers in April 2021. Manufacturers were asked to undertake a risk assessment and notify the MHRA of planned action in relation to products sold into the UK. As of 29 June 2021, twenty-eight manufacturers have informed the MHRA of field safety corrective actions (FSCA) relating to Steril Milano. Where the UK is affected, all manufacturers' field safety notices (FSNs) relating to Steril Milano are in this folder.

The MHRA has prioritised engagement with affected manufacturers known to have significant supply into the UK. It has conducted thorough risk assessments and has worked with cross-system groups to minimise disruption and ensure appropriate actions. Amongst others, MHRA has worked with DHSC Supply Resilience team, the devolved administrations, NHSE&I, Public Health England, National Clinical Cells, patient groups, manufacturers, NHS Supply Chain, sterilisation facilities and notified bodies.

Work undertaken includes sharing risk assessments to inform clinical decision-making, negotiating with manufacturers to ensure the feasibility of actions in FSNs and developing supporting guidance for healthcare professionals and patients. This joint work has led to the MHRA publishing additional safety information relating to specific manufacturers:

National Patient Safety Alert: Supply disruption of sterile infusion sets and connectors manufactured by Becton Dickinson (BD) (NatPSA/2021/001/MHRA).

MDSI2104, *Total parenteral (TPN) and enteral nutrition bags manufactured by Diffuplast: Sterilisation issue*, issued by Health Facilities Scotland on 21 April 2021.

MHRA is collaborating with international medical device regulators, sharing best practice and information on field safety corrective actions and recalls.

Action

- This notice should be brought to the attention of all appropriate managers, staff and users.
- Review the folder of field safety notices to check whether your local authority or health board has purchased affected devices: click here
- Report any suspected infections involving affected devices to your local incident management system (often referred to as Datix) and to IRIC: Report an incident

Enquiries and further information

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

For information on how to report an incident: How to report an Adverse Incident

General information about adverse incidents and safety alerts can be found in CEL 43 (2009) or by contacting IRIC at the above address.