MHRA Device Safety Information

MDSI (SC) 21/05 06 May 2021

Recall of BD Venflon Pro safety IV cannula

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 04 May 2021. The original webpage can be accessed here.

Summary

Becton Dickinson (BD) is recalling specific lots of BD Venflon Pro Safety (VPS) Needle Protected IV Cannulae after identifying an increase in reports of leakage from the injection port.

Background

Becton Dickinson (BD) has identified an issue with specific lots of BD Venflon Pro Safety (VPS) Needle Protected IV Cannulae after identifying an increase in reports of leakage from the injection port. BD has issued an updated Field Safety Notice (FSN) and is recalling all products sterilised by ethylene oxide (EtO). It does not affect products sterilised by electron beam. Check the FSN for affected product codes and details on how to identify sterilisation methods used.

Risk involved with using affected product
There is a risk of blood or fluid loss from the injection port, which can result in serious harm if undetected. Reported issues to date include: minor to severe blood loss, delay to treatment, failure of cannula leading to replacement, and non-delivery of critical medications.

Information from the manufacturer indicates an increased risk with larger cannulae and if the devices are used in combination with rapid pressurised fluid infusers.

Action

Actions for NHS Boards

- NSS National Procurement is co-ordinating a logistics response which will be the subject of Product Recall Notice PR326.
- Health Boards should follow the actions in PR326 which differ slightly from those below.

Actions for local authorities and all other affected care providers

1. Identify and procure suitable alternative vascular access devices.
2. Ensure that there is adequate supply of alternatives in clinical areas to maintain care provision.
3. Ensure clinicians are informed of the change.
4. Follow recall actions in the FSN. Always act on FSNs issued by manufacturers. Do not wait for a communication from the MHRA.
5. Report any suspected or actual adverse incidents involving these devices through your healthcare institution's local incident reporting system and/ to IRIC

Enquiries and further information

Enquiries (and adverse incident reports) in Scotland 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

Reporting options are available on the HFS website: How to report an Adverse Incident

Further information about reporting incidents can be found in CEL 43 (2009) or by contacting IRIC at the above address.