MHRA Device Safety Information

MDSI2107 20 May 2021

Recall of BD Venflon Pro safety and Venflon Pro IV cannula

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 20 May 2021. The original webpage can be accessed here.

Summary

Becton Dickinson (BD) is recalling all ethylene oxide (EtO) sterilised BD Venflon Pro Safety (VPS) and Venflon Pro IV Cannulae after identifying an increase in reports of leakage from the injection port.

Background

BD has updated its Field Safety Notice (FSN) information and is now also recalling Venflon Pro products sterilised by ethylene oxide (EtO). It does not affect products sterilised by electron beam. Check both the FSNs for affected product codes and details on how to identify sterilisation methods used: BD Venflon Pro safety IV cannula FSN BD Venflon Pro IV Cannula FSN

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
- 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

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 Venflon Pro Safety FSN and Venflon Pro IV Cannula 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/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales

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.