Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/046 Issued: 19 December 2019 at 12:00 Valid until January 2020

Arrow EZ-IO intraosseous vascular access needle sets – risk of needle stick injury

Summary

Manufactured by Teleflex Medical (Arrow) – do not use needles if the safety cap is not in place as the risk of needle stick injury is increased and sterility of the needle may be compromised if packaging is punctured.

Action

- Identify affected devices and check that the safety cap is attached to the needle (see manufacturer's Field Safety Notice dated 3 October 2019).
- If the safety cap is not in place, dispose of devices in line with your local procedures.
- Contact Teleflex to have your account credited.
- Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Action by
Users of the device and those responsible for procurement/stock management.

Deadlines for actions
Actions underway: 14 January 2020
Actions complete: 28 January 2020

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Department of Health An Roinn Sláinte Männystrie O Poustie www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

The affected product codes are listed in the manufacturer's Field Safety Notice.

In addition, for some of the affected product codes these are the National Supply Chain codes for England:

NPC	Secondary Product Description	Supplier Code / MPC	Supply Route
FSN323	15G x 45mm Yellow with stabilizer Dressing Extension Set Patient Wrist Band and Sharps Block	9079P-EU-005	Blue Diamond
FSN324	15G x 25mm Blue with stabilizer Dressing Extension Set Patient Wrist Band and Sharps Block	9001P-EU-005	Blue Diamond
FSN326	15G x 15mm Pink with stabilizer Dressing Extension Set Patient Wrist Band and Sharps Block	9018P-EU-005	Blue Diamond

In addition to the manufacturer's Field Safety Notice, which details affected product, the table below gives the unique device identifier codes for some of the products.

Device Identifier GTIN	Catalogue number (Manufacturer product code)	Product description
Single: 00816000011898 Pack: 10816000011895 Case: 20816000011892	9018P-VC-005	15mm Needle + Stabilizer Kit (9018P)
Single: 00816000011881 Pack: 10816000011888 Case: 20816000011885	9001P-VC-005	25mm Needle + Stabilizer Kit (9001P)
Single: 00816000011904 Pack: 10816000011901 Case: 20816000011908	9079P-VC-005	45mm Needle + Stabilizer Kit (9079P)

Manufacturer contacts

Teleflex Medical
Tel: 01494 532 761
Email: orders.uk@teleflex.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- Ambulance services directors

- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Supplies managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
- Hospitals in the independent sector

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/046** or **2019/010/003/487/012**.

Technical aspects

Enitan Taiwo or Eliz Mustafa, MHRA
Tel: 020 3080 6000
Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA
Tel: 020 3080 7274
Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)
Tel: 028 9052 3868
Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 255278 or 03000 255510

Email: Haz-Aic@gov.wales

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).