Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/014 Issued: 20 April 2020 at 11:00 Valid until April 2021

Pilling Clear Advantage aortic punch – risk of infection due to packaging failure

Summary

Manufactured by Teleflex – if the packaging is not intact, the device won't be sterile.

Action

- Identify and quarantine affected devices. Check the manufacturer's Field Safety Notice (FSN) for the relevant product codes and lot numbers.
- The devices are supplied as part of procedure packs supplied by other companies such as Molnlycke so check the separate FSN issued by Molnlycke and follow the instructions provided.
- Return unused, affected stock to the manufacturer or supplier.
- 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
All staff involved in purchasing, storage and use of theatre products.

Deadlines for actions
Actions underway: 04 May 2020
Actions complete: 03 June 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

These devices are supplied directly from the manufacturer or via distributors.
They are also supplied as part of procedure packs by other companies such as Molnlycke.

In addition to the manufacturer's Field Safety Notice, which details affected product, refer to the spreadsheet which accompanies this MDA for additional unique device identification information.

Problem / background

This alert is being issued because the manufacturer hasn't received enough replies to their FSN.

Manufacturer contacts

Teleflex Medical Customer Services
Cliodhna Coffey
Tel: 01494 532761
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:

- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Risk managers
- Theatre managers
- Theatre nurses
- Theatres

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/2020/014 or 2020/001/030/487/001

Technical aspects

Sara Vincent, 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).