Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/019 Issued: 25 April 2019 at 14:00 Valid until April 2020

Ethicon Curved Intraluminal Staplers – risk of failure of staple lines

Summary

Manufactured by Ethicon – use of affected devices may result in failure of staple line which could lead to postoperative anastomotic leaks, gastrointestinal tissue injury and bleeding.

Action

- Ensure all relevant members of staff receive the manufacturer's Field Safety Notice dated 29 March 2019.
- Actions are:
  1. Identify and quarantine all affected, unused devices as listed in the Field Safety Notice.
  2. If alternative devices are available, use the alternatives and return affected products to Ethicon.
  3. If alternative devices are not available, only use affected products following local risk assessment and in adherence to the guidance provided in the Field Safety Notice.
  4. Complete the Business Response Form and return to Ethicon.

- Report 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 and healthcare professionals who are responsible for purchasing or who use these devices.

Deadlines for actions
Actions underway: 09 May 2019
Actions complete: 23 May 2019

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

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

Problem / background

Affected devices have been manufactured since March 2018 with expiry dates in 2023. The problem was identified following increased complaints of malformed staples and returned devices from customers. The manufacturer expects failure rate to remain below 0.1%. A root cause investigation is ongoing.

Manufacturer contacts

Ethicon LLC, Johnson & Johnson Medical
Tel: 0113 387 6261
Email: MDFieldActionsUKIrl@its.jnj.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:

- Adult intensive care units
- Day surgery units
- Equipment stores
- Equipment libraries and stores
- Gastro-intestinal surgeons
- General surgeons
- General surgery
- General surgical units, directors of
- Gynaecologists
- Gynaecology departments
- Gynaecology nurses
- Medical directors
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Operating department practitioners
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric surgeons
- Paediatric surgery, directors of
- Purchasing managers
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of
- Urology departments

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/019** or **2019/003/028/701/016**.

Technical aspects

Emma Harris, 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, Social Services and Public Safety

Tel: 0208 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 250986 / 03000 255510

Email: haz-aic@wales.gov

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).