

Medical Device Alert

Action

Ref: MDA/2011/022 Issued: 02 March 2011 at 11:00

Device

Sutures manufactured by ETHICON:

- ETHILON – monofilament nylon
- ETHIBOND – polybutylate coated braided polyester
- MERSILENE – braided polyester
- MERSILK – braided silk

Affected product codes and lot numbers are identified in manufacturers [Field Safety Notice](#)

Problem	Action
<p>The unit pack in the affected products may not have a complete seal and so the contents may not be sterile.</p> <p>There is a risk of infection if non-sterile sutures are used.</p>	<p>Follow the actions set out in ETHICON's Field Safety Notice dated 29 December 2010. These are:</p> <ul style="list-style-type: none"> • Do not use affected products • Locate and quarantine affected products • Return affected products to your distributor or ETHICON along with their 'Recall Confirmation Form'.
<h3>Action by</h3> <p>All staff who use these sutures.</p>	
CAS deadlines	Contact
<p>Action underway: 09 March 2011</p> <p>Action complete: 06 April 2011</p>	<p>Ethicon Products Division, J&J Medical Ltd Mr Mark Struthers QA Manager Tel: 01506 594500 Email: Complaints@ethgb.JNJ.com</p>

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- All clinical departments
- All staff
- All wards
- A & E departments
- Ambulance staff
- Clinical governance leads
- Day surgery units
- Intensive care units
- Maternity units
- Obstetric theatres
- Purchasing managers
- Sterile services managers
- Supplies managers
- Surgeons
- Theatres
- Theatre nurses

Primary care trusts

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

- Community hospitals
- Community midwives
- Community nurses
- General practitioners
- General practitioners – out of hours emergency centres
- Minor injury units
- NHS walk-in centres
- Practice managers
- Practice nurses
- Walk-in centres

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

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 Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer

Ethicon Products Division, J&J Medical Ltd

Mr Mark Struthers, QA Manager

Simpson Parkway

Kirkton Campus

Livingston

West Lothian

EH54 7AT

Tel: 01506 5944500

Email: Complaints@ethgb.JNJ.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/022** or **2010/012/029/601/002**

Technical aspects

Allan Hidderley or Ian Smith

Medicines & Healthcare products Regulatory Agency

Floor 4

151 Buckingham Palace Road

London SW1W 9SZ

Tel: 020 3080 7172/7306

Fax: 020 8754 3965

Email: allan.hidderley@mhra.gsi.gov.uk
ian.smith@mhra.gsi.gov.uk

Clinical aspects

Dr Nicola Lennard

Medicines & Healthcare products Regulatory Agency

Floor 4

151 Buckingham Palace Road

London SW1W 9SZ

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Fax: 020 8754 3965

Email: nicola.lennard@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre

Health Estates Investment Group

Room 17

Annex 6

Castle Buildings

Stormont Estate

Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: nss.irc@nhs.net

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

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