

Medical Device Alert

Ref: MDA/2011/057 Issued: 26 May 2011 at 14:00

Device

BLAKE[®] Silicone Drain
 BLAKE[®] Silicone Drain Kit
 BLAKE[®] Cardio Connector
 J-VAC[™] Reservoir
 J-VAC[™] Drain Adapter

Manufactured by Ethicon

Multiple product codes and lot numbers.

Problem	Action
<p>The manufacturer issued a Field Safety Notice (FSN) for this device on 24 March 2011.</p> <p>However the MHRA cannot be confident that the recall action has been effective and that users have received and acted on this information.</p> <p>A copy of the FSN is in the appendix of this Alert, and it is also available on the MHRA website.</p> <p>This Alert has been issued in support of the manufacturer's actions.</p>	<p>If you are affected by this FSN;</p> <ul style="list-style-type: none"> • Ensure that relevant members of staff are aware of the problem. • Carry out the actions described in the manufacturer's FSN, including sending any confirmation requests.
Action by	
<p>All healthcare workers who use these devices.</p> <p>Personnel involved in the purchase, supply and distribution of these devices.</p>	
CAS deadlines	Contact
<p>Action underway: 13 June 2011</p> <p>Action complete: 27 June 2011</p>	<p>Manufacturer Mark Struthers Ethicon Products – J&J Medical Ltd Tel: 01506 594 907 Fax: 01506 594 756 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)

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 surgeons
- Clinical governance leads
- Day surgery units
- Intensive care units
- Medical directors
- Nursing executive directors
- Risk managers
- Surgical wards
- Supplies managers
- Theatre managers

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres

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

Mark Struthers
Ethicon Products – J&J Medical Ltd
Simpson Parkway
Kirkton Campus
Livingston
West Lothian
EH54 7AT

Tel: 01506 594 907

Fax: 01506 594 756

Email: complaints@ethgb.jnj.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/057** or **2011/003/024/601/001**

Technical aspects

Ainsley Wickens or Sara Vincent
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7273 / 7169

Fax: 020 8754 3965

Email: ainsley.wickens@mhra.gsi.gov.uk
sara.vincent@mhra.gsi.gov.uk

Clinical aspects

Jonathan Plumb
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7128

Fax: 020 8754 3965

Email: jonathan.plumb@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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Addressees may take copies for distribution within their own organisations

Appendix

ETHICON

URGENT VOLUNTARY PRODUCT RECALL

**BLAKE® Silicone Drain
BLAKE® Silicone Drain Kit
BLAKE® Cardio Connector
J-VAC™ Reservoir
J-VAC™ Drain Adapter
Multiple Product Codes and Lots (See Enclosed List)**

March 24th 2011

Dear Customer:

**PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR DEPARTMENT
WHO USE THE ABOVE LISTED PRODUCTS**

Ethicon, Inc. is voluntarily recalling multiple lots of BLAKE® Silicone Drains, BLAKE® Silicone Drain Kits, BLAKE® Cardio Connectors, J-VAC™ Reservoirs and J-VAC™ Drain Adapters, with distribution dates of May 10, 2010 through February 28, 2011. The company identified the potential for the sterile barrier of the product packaging to be compromised after receiving customer complaints. Please see enclosed list of product codes and lot numbers impacted by this voluntary recall action (Attachment 1). We have not received any reports of adverse events related to this issue. The United States Food and Drug Administration (FDA) as well as the UK MHRA have been notified of this action.

We are requesting that customers immediately discontinue use of products from the list of product codes and lot numbers attached. This recall is limited to the product names, product codes and lot numbers included in the enclosed list, *Attachment 1*. Please refer to *Attachment 2* for additional information and photographs illustrating how to check your product inventory to determine whether or not you have any product impacted by this voluntary recall.

If you are in possession of product labelled with affected product codes and lot numbers you should discontinue its use immediately. Remove the recalled product from your inventory and return it according to the instructions provided below.

- Immediately quarantine any of the recalled products listed in attachment 1 from your inventory (Physical quarantine – cage or other suitable restriction to access)
- Check with your customers if they still have any of the listed products in their Stock. If yes: have the products sent back as soon as possible.

Send any recalled product returned to you to the following address within 30 days:

EDC
European Distribution List
ATT:Mr Arnaud Langue
5 Rue de Luxembourg
B -6180 Courcelles, Wallonia
Belgium

a division of JOHNSON & JOHNSON MEDICAL LIMITED

PO Box 1988, Simpson Parkway, Kirkton Campus, Livingston, EH54 0AB
Telephone: 01506 594500 Fax: 01506 460714 www.ethiconproducts.co.uk Reg No. SC 132162

Please enclose a copy of the Recall Confirmation Form (attached here) with the recalled product you are returning and also send a scanned copy of the form (with signature) along with the courier tracking no. of your shipment to complaints@ethgb.jnj.com. Alternatively, you may send a copy of the form to J&J Medical Ltd (Simpson Parkway, Kirkton Campus, Livingston, West Lothian, EH54 7AT) or transmit the form via fax (+44(0)1506 594756).

Please disseminate this notice to those within your organization who need to be aware of this action or to any organization where the potentially affected devices have been transferred.

The undersigned confirms that this notice has been notified to the appropriate European Regulatory Agency.

Kind Regards
J&J Medical Ltd

Mark Struthers
Quality Assurance Manager
European Authorized Representative

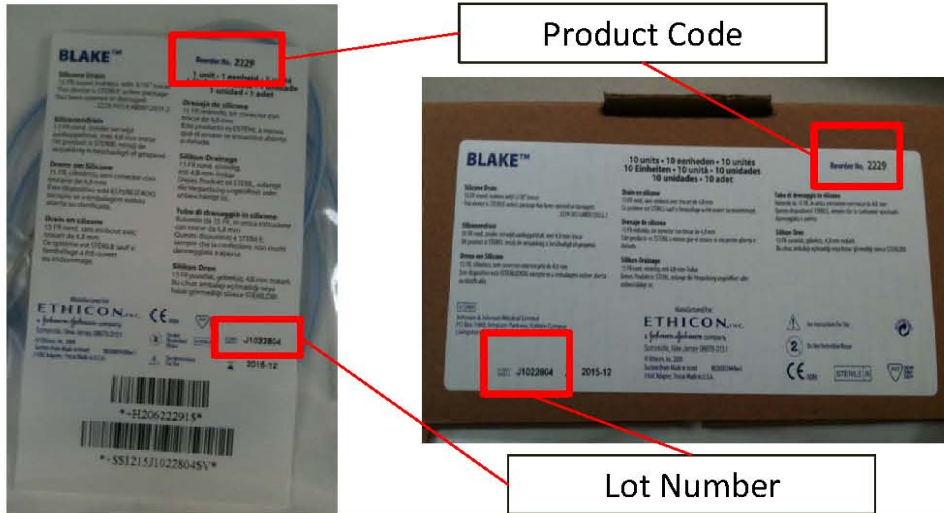
Tel: +44(0)1056 594907
Fax: +44(0)1506 594756

Enclosures: Attachment 1: Product Codes and Lot Numbers Impacted by Recall
Attachment 2: How to Identify Recalled Product

Attachment 2 - How to Identify Recalled Product

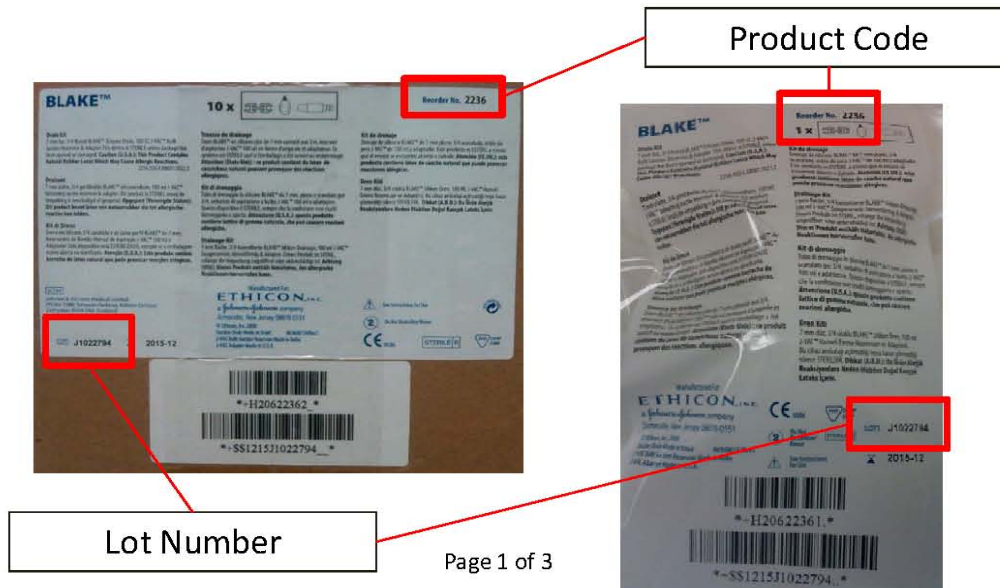
BLAKE® Silicone Drains

Product Codes: 2210, 2211, 2212, 2213, 2214, 2215, 2216, 2217, 2226, 2227, 2228, 2229, 2230, 2231, 2232, 2233, 2234



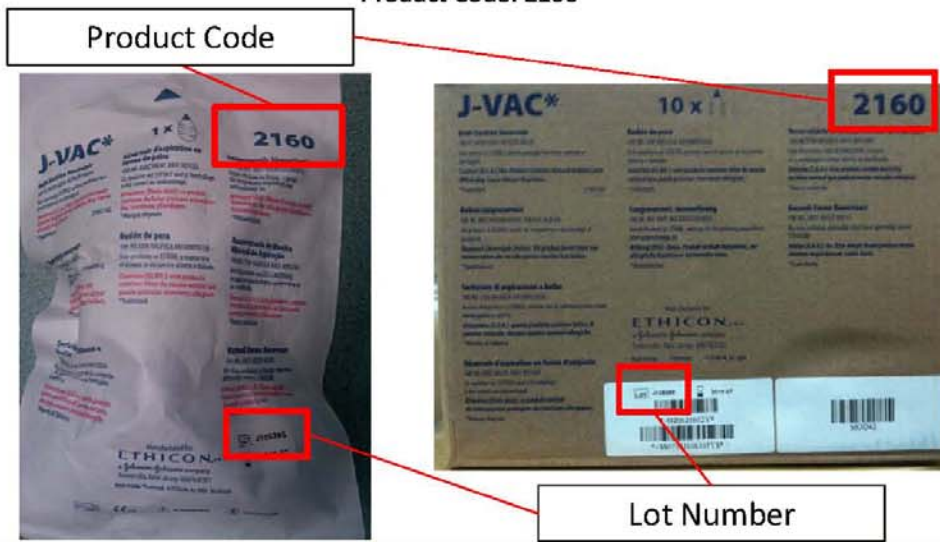
BLAKE® Silicone Drain Kit

Product Codes: 2205, 2207, 2236, 2238, 2268



Attachment 2 - How to Identify Recalled Product

J-VAC™ Reservoir Product Code: 2160



BLAKE® Cardio Connectors Product Codes: BCC1, BCC2, BCC3



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Attachment 2 - How to Identify Recalled Product

J-VAC™ Drain Adapter Product Code: 2199

