

Medical Device Alert

Ref: MDA/2011/0052 Issued: 19 May 2011 at 15:00

Device

Topical skin adhesive.

Dermabond® (product code AHV12 Lots: CJP841 and CKE811) and Dermabond™ Mini (product code AHVM12 Lot: CKE512).

Manufactured by Ethicon Products, J&J Medical Ltd

Problem	Action
<p>The manufacturer issued a Field Safety Notice (FSN) for this device on 4 February 2011, but has not had sufficient confirmation from users that they 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>	<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 staff using these skin adhesives, suppliers and distributors</p>	
CAS deadlines	Contact
<p>Action underway: 06 June 2011</p> <p>Action complete: 20 June 2011</p>	<p>Manufacturer Mr Mark Struthers 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)
- 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:

- A&E departments
- A&E nurses
- All theatres
- All wards
- General surgeons
- Medical directors
- Nursing executive directors
- Pharmacy
- Purchasing managers
- Risk managers
- Theatre managers

Primary care trusts

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

- Community children's nurses
- Community nurses
- District nurses
- General practitioners
- Health visitors
- Minor injury units
- NHS walk-in centres
- Practice managers
- Practice nurses

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
- Private medical practitioners

Please note: CQC does 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

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/2011/052** or **2011/002/004/601/006**

Technical aspects

Sally Mounter or Nicola Harris
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7168 / 6243

Fax: 020 8754 3965

Email: sally.mounter@mhra.gsi.gov.uk
nicola.harris@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

**URGENT VOLUNTARY PRODUCT RECALL
DERMABOND® Topical Skin Adhesive
DERMABOND™ Mini Topical Skin Adhesive
Product Codes AHV12 and AHVM12
Multiple Lots (See Enclosed List)**

February 4, 2011

Dear Customer:

**PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR DEPARTMENT
WHO USE DERMABOND® Topical Skin Adhesive & DERMABOND™ Mini Topical Skin
Adhesive**

Ethicon, is voluntarily recalling multiple lots of DERMABOND® Topical Skin Adhesive and DERMABOND™ Mini Topical Skin Adhesive based on reports that some units contained discolored product in the vial, and may also have had prolonged setting times. Please see attached list of recalled lot numbers (*Attachment 1*). We have not received any reports of adverse events related to these occurrences. 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 DERMABOND® Adhesive units that come from the affected lots. The attached document will show you how to check your product (*Attachment 2*). This recall is limited to DERMABOND® Topical Skin Adhesive and DERMABOND™ Mini Topical Skin Adhesive lot numbers included in the attached list, and product codes AHV12 and AHVM12. A credit will be provided for all affected product returned. **No other product should be returned. We cannot provide a credit for any returned product that is not part of the recalled lot numbers and product codes.**

If you are in possession of product labeled 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

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

Attachment 1

**DERMABOND® Topical Skin Adhesive
DERMABOND™ Mini Topical Skin Adhesive**

Recalled Lots

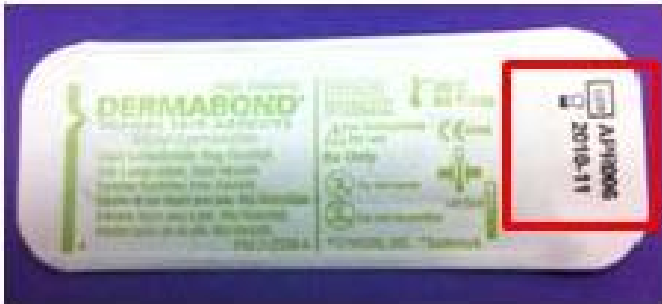
Product Name	Product Code	Lot #	Product Expiration Date
DERMABOND® Topical Skin Adhesive	AHV12	CJP841	7/31/2012
DERMABOND® Topical Skin Adhesive	AHV12	CKE811	8/31/2012
DERMABOND™ Mini Topical Skin Adhesive	AHVM12	CKE512	8/31/2012

Attachment 2 - How to Identify Recalled Product

DERMABOND® Topical Skin Adhesive

Product Code

Lot Number



Lot Number

DERMABOND® Mini Topical Skin Adhesive

Product Code

Lot Number



Lot Number

Recall Confirmation Form

Form Name (#): FM-0000204
Revision: 2

SURVEY

Name: _____
Address: _____

Country: _____
Contact: _____
Contact Phone Number: _____
Contact Fax Number: _____

Number of Boxes of Product in Your Inventory: -----n/a*-----
Number of Customers Possibly Receiving Product: -----n/a *-----
Number of Boxes / Eaches Returned by Customers: ___n/a*___ Boxes ___n/a*___ Eaches
Number of Boxes / Eaches destroyed or shipped for destruction¹ ___n/ a*___ Boxes ___n/ a*___ Eaches

*For quantities please see attachment 1

Please provide information requested and fax the form to:

J&J Medical Scotland

Fax: 01506 594756

Or send a scanned copy with signature to complaints@ethgb.jnj.com

Recall Confirmation Form

Form Name (#): FM-0000204

Revision: 2

Attachment 1

Please fill in the quantity of devices you received in the first place, quantity still at your customers, quantity already used, and the quantity that will be sent back to Ethicon for each Product Code.

Sales code	Lot #	Devices/ Eaches delivered	Devices/ Eaches in customer's stock	Devices/ Eaches already used	Devices/ Eaches that will be sent back
AHV12	CKE811				
AHVM12	CKE512				
AHV12	CJP841				