# 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
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 <a href="mailto:complaints@ethgb.jnj.com">complaints@ethgb.jnj.com</a>. 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

Quality Assurance Manager European Authorized Representative

Tel: +44(0)1056 594 Fax: +44(0)1506 594756

#### **Attachment 1**

### DERMABOND® Topical Skin Adhesive DERMABOND™ Mini Topical Skin Adhesive

#### **Recalled Lots**

Product Name	Product	Lot #	Product Expiration
	Code		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

