

May 18, 2011

Encik Zamane Bin Abdul Rahman  
Medical Device Bureau  
Ministry of Health Malaysia  
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Persiaran Perdana, Precint 3  
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## **URGENT VOLUNTARY PRODUCT RECALL**

**BLAKE® Silicone Drain**  
**Updated Attachment Includes:**  
**Lot J1015422 of Product Code 2234, and Lot J1010652 of Product Code 2227**

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Dear Sirs:

This letter is to inform you that ETHICON inc. has expanded the voluntary product recall of Ethicon BLAKE® Silicone Drain to include two (2) additional lots of product as listed in Attachment 1.

### **Summary**

On March 28, 2011, Ethicon Inc. voluntarily recalled 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 due to the potential for the sterile barrier of the product packaging to be compromised.

### **Actions**

As previously communicated, we had identified multiple affected lots (total of 27 lots) imported into Malaysia. We have identified 2 additional lots imported into Malaysia as per attachment 1. We will immediately quarantine all of the recalled products listed from our inventory.

### **Communication of this Field Action**

All our customers have been notified to return all recalled product to our distributor. Credit Notes will be provided for all returned materials. The product codes and lot numbers are printed on container boxes.

ETHICON also confirms that this notice has been notified to the United States Food and Drug Administration (FDA).

If you require additional information regarding this matter, please contact the Johnson & Johnson Regulatory Affairs Manager on +603 7962682.

Kind Regards



**Ong Yean Ting**  
Johnson & Johnson Sdn Bhd, Medical Division  
Regulatory Affairs Manager

**Attachment 1: Product Codes and Lot Numbers Impacted by  
Voluntary Product Recall**

Material Product Code	Batch
2227	J101418
2227	J101420
2227	J102696
2227	J103191
2227	J107779
<b>2227</b>	<b>J107778</b>
<b>2227</b>	<b>J1010652</b>
2227	W00023338
2229	J101771
2229	J101772
2229	J102268
2229	J103791
2229	J105288
2229	J105291
2229	J105295
2231	J100005
2231	J100301
2231	J100303
2231	J100304
2231	J100589
2231	J100591
2231	J101818
2231	J106001
2231	W00022364
2231	W00024341
2231	W00024389
2234	J101125
2234	J1013983
2234	J106715