March 28, 2011

Encik Zamane Bin Abdul Rahman
Medical Device Bureau
Ministry of Health Malaysia
Level 5, no 26 Boulevard Plot 3C4
Persiaran Perdana, Precint 3
62675 Putrajaya, Malaysia

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)_

Dear Sirs:

This letter is to inform you that 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.

Summary

As a precautionary measure, 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) due to the potential for the sterile barrier of the product packaging to be compromised. To date, the company has not received any reports of adverse events related to this product.

Based on an Ethicon investigation to understand the root cause of the issue, it appears that human error at an external manufacturer may have contributed to the potential issue. Drains and drainage systems, such as those impacted by this voluntary recall, can be used following a surgical procedure to remove potentially detrimental collections of certain fluids (e.g. pus, blood, bile) from wounds.

Johnson & Johnson Sdn. Bhd. (3718-D)
Ground Floor, G.01, Block B, 10, Jalan Bersatu 13/4,
46200 Petaling Jaya, Selangor Darul Ehsan, Malaysia
Tel: (603) 7962 6800 Fax: (603)7955 3290

Actions

We have identified multiple affected lots (total of 27 lots) imported into Malaysia as per attachement 1. We will immediately quarantine any of the recalled products listed from our inventory.

Communication of this Field Action

All our customers will be 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
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

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