



Medical Devices Bureau, Ministry of Health Malaysia
 Level 5, Block E6, Complex E,
 Federal Government Administrative Centre,
 62590 Putrajaya, MALAYSIA.
 Tel: 03-8883 2248/2249/2264
 Fax: 03-8888 6184

Medical Device / Equipment **RECALL**

Date Issued : 22nd August 2008

Ref:MDB/R/2008/013

IMMEDIATE ACTION	√
ACTION	√
UPDATE	
INFORMATION REQUEST	

PRODUCT	All Lots of Cordis LuMend OUTBACK LTD Re-Entry Catheter – Catalog Number OTB42120
CLASS	Not Mentioned
USE	Catheter
SOURCE OF MEDICAL DEVICE RECALL / ALERT	Communication by electronic mail sent to Medical Device Bureau via Johnson & Johnson Sdn. Bhd., Medical Division Malaysia.
RECALLING / ALERTING FIRM	Johnson&Johnson Sdn. Bhd., Medical Division *Cordis is initiating a global recall of all lots of the above mentioned product.
REASON FOR RECALL/ALERT	<i>Refer attachments for details</i>
SCENARIO IN MALAYSIA	<i>Refer attachments for details</i> <i>According to Johnson&Johnson Malaysia, lot number 13371134 and number 13382308 is sent to the customers in Malaysia.</i> <i>No details available at this moment.</i>
ACTION	<i>Refer attachments for details</i>
RECOMMENDATION	Users of the abovementioned device (if available) should contact the distributors/supplier of this device and inform the Medical Devices Bureau, Ministry of Health providing the following information:-

	<p>a. Name of healthcare centre/hospital/clinic b. Contact person and contact number c. Numbers of units available</p>
CONTACT/ENQUIRIES	<p>Ong Yean Ting, Johnson&Johnson Sdn. Bhd., Medical Division 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor.</p> <p>T: 603 79555108 F: 603 79553290</p>
REFERENCES FOR DETAILS	<p><i>Refer attachments for details</i></p>

August 20, 2008

Dr. Ahmad Mahmud
Director
Medical Device Bureau, Ministry of Health Malaysia
Block E6, Level 5, Complex E, Federal Government Administrative Centre,
62590 Putrajaya, MALAYSIA.

**RE: Voluntary Product Recall of All Lots of Cordis LuMend OUTBACK[®] LTD[®] Re-Entry Catheter
Catalog Number OTB42120**

Dear Sir :

This letter is to inform you that Cordis is conducting a voluntary product recall of all lots of Cordis LuMend OUTBACK[®] LTD[®] Re-Entry Catheter Catalog Number OTB42120.

Description of Event

Cordis is initiating a global recall of all lots of the Cordis LuMend OUTBACK[®] LTD[®] Re-Entry Catheter Catalog Number OTB42120. This recall is initiated because Cordis has recently determined that the separation rate of the cannula to the deployment slide of the handle assembly of the LuMend Outback[®] LTD[®] Re-Entry Catheter is higher than anticipated. The potential result of such a separation is inability to retract the cannula needle into the cannula body. If a separation of the cannula and the deployment slide of the handle assembly were to occur during use and the cannula tip remained extended, the device may need to be removed percutaneously with the needle in the deployed position or via surgical extraction. In such cases, vascular injury is a possibility. If a procedure has been completed successfully using the product, there is no concern.

No injuries or Adverse Events have been reported in Malaysia till date.

This recall only applies to all lot numbers LuMend OUTBACK[®] LTD[®] Re-Entry Catheter Catalog number OTB42120 as attached in Enclosure.

Recall Strategy

We wish to inform that in Malaysia, our records show that we have imported LuMend OUTBACK[®] LTD[®] Re-Entry Catheter Catalog Number OTB42120. However, all the units have been quarantined in our warehouse and no units have been distributed. Therefore no recall notifications will be sent to Hospitals / Institutions/ Distributors.


The voluntary recall is being conducted with the full knowledge of the US Food & Drug Administration (FDA).

Yours sincerely,



Ong Yeán Ting
Regulatory Affairs Manager

Encl: List of Lots being Recalled



Customer name	Customer # DCS/EDO	Catalogue #	Lot #	Invoice # / order #	Invoice date / ship date	QTY	QTY blocked/ destroyed
Malaysia	4131	OTB42120	13371134	1728554	27/May/2008	1	1
Malaysia	4131	OTB42120	13382308	1782153	24/Jun/2008	2	2