**Medical Devices Bureau, Ministry of Health Malaysia**
**Level 5, Block E6, Complex E,**
**Federal Government Administration Centre,**
**62590 Putrajaya, MALAYSIA**
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# Medical Device / Equipment RECALL

**Date Issued : 28 April 2008** **Ref:MDB/R/2008/005**

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| **IMMEDIATE ACTION** | √ |
| **ACTION** | |
| **UPDATE** | |
| **INFORMATION REQUEST** | |

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| **PRODUCT** | **IntraStent Unmounted Balloon Expandable Stent** |
| **CLASS** | n/a |
| **USE** | The manufacturer, ev3, has advised the Irish Medicines Board (IMB) of a recall of specific lots of the IntraStent Unmounted Balloon Expandable Stent.<br><br>The manufacturer has confirmed that the following affected lot / serial numbers have been supplied to the Irish market:<br>Affected batch numbers are recognized as:-<br>**4206244, 1688027, 1979986, 3003378** |
| **SOURCE OF MEDICAL DEVICE RECALL / ALERT** | **Irish Medicines Board website, date issued: 24th January 2008** |
| **ALERTING / RECALLING FIRM** | **In Ireland (as reported through the IMB website):-**<br><br>ev3 Limited<br>1 Twyford Business Centre<br>London Road<br>Bishop's Stortford<br>Herts, CM23 3YT<br>United Kingdom<br><br>Telephone: +44-1-279-659-900<br>Fax: +44-1-279-654-900 |

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| | Email: posullivan@ev3.net |
| **REASON** | The IntraStent is a peripheral / biliary stent.<br><br>The manufacturer initiated the recall of certain lots of this product following the discovery that two symbols (the symbol for length and the symbol for diameter) on the side and end-flaps of IntraStent boxes in the affected lots are reversed. The length and diameter symbols on the top of the box and on the device pouch are correct.<br><br>*In Republic Of Ireland, these potentially affected lots of this product were supplied to the Irish market in the year 2007 by Lecks Medical.<br><br>The IMB had decided that there is no action required with devices that have already been implanted. |
| **SCENARIO IN MALAYSIA** | **No details available at this moment about this device and its existence in our market.** Please check whether the device is available in your database and contact the distributor for further action. |
| **ACTION** | 1. Ensure that the relevant personnel in your organisation are made aware of this recall.<br>2. Determine if you have purchased the affected lots of this product.<br>3. If available, quarantine and return any unused affected product to the supplier/distributor for further action.<br>4. Advise the distributor/supplier of this products and the Medical Device Bureau if you have the affected product. |
| **RECOMMENDATION** | Users of the abovementioned device should contact the distributor/supplier of this device (if available) and **inform the Medical Devices Bureau, Ministry of Health** providing the following information:-<br><br>a. Name of healthcare centre/hospital/clinic<br>b. Contact person and contact number<br>c. Numbers of units available |

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| **CONTACT/ENQUIRIES IN MALAYSIA** | Currently No Information Available. |
| **REFERENCES / ORIGINAL SOURCE OF NOTIFICATION** | http://www.imb.ie/EN/Safety--Quality/Advisory-Warning--Recall-Notices/Medical-Devices/IntraStent-Unmounted-Balloon-Expandable-Stent.aspx?page=1&noticetypeid=-1&year=-1 |