



IRISH MEDICINES
BOARD

MEDICAL DEVICE SAFETY NOTICE

INTRA STENT **IMB Safety Notice: SN2008(01)**

MANUFACTURER/SUPPLIER

Ev3, United Kingdom.

TARGET GROUPS

Hospital Chief Executive Officers
Hospital Risk Managers
Vascular Surgery
Gastrointestinal Surgery
Gastroenterology
Interventional Radiology
Surgical Departments

ISSUE

The manufacturer, ev3, has advised the Irish Medicines Board (IMB) of a recall of specific lots of the IntraStent Unmounted Balloon Expandable Stent.

The manufacturer has confirmed that the following affected lot / serial numbers have been supplied to the Irish market:

4206244 1688027 1979986 3003378

BACKGROUND

The IntraStent is a peripheral / biliary stent.

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.

The potentially affected lots of this product were supplied to the Irish market in the year 2007 by Lecks Medical.

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NOTICE

No action is required with devices that have already been implanted.

ACTION OR RECOMMENDATIONS

1. Ensure that the relevant personnel in your organisation are made aware of this recall.
2. Determine if you have purchased the affected lots of this product.
3. Quarantine and return any unused affected product to ev3, United Kingdom office (see address below).
4. Advise the IMB if you have the affected product.

ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Medical Devices Department
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

If you have any enquiries, you may contact the Medical Devices Department at:

Telephone: +353-1-6764971
Fax: +353-1-6344033
Email: vigilance@imb.ie
Website: www.imb.ie

Enquiries to the manufacturer should be addressed to:

Ms. Paula O'Sullivan
ev3 Limited
1 Twyford Business Centre
London Road
Bishop's Stortford
Herts, CM23 3YT
United Kingdom

Telephone: +44-1-279-659-900
Fax: +44-1-279-654-900
Email: posullivan@ev3.net

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