

Notice Information: Medical Devices - Recall 24 January 2008

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Serial/Batch Number & Expiry Date:
- e) Manufacturer/Supplier:

Part 2. Target Audience

- a) Target Audience:

Part 3. Problem/Issue

- a) Problem/Issue:

Part 4. Background Information

a) Background Information:

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

Part 5. Action to be taken

a) Action to be taken:

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

Part 6. Enquiries

a) All enquiries should be made to:

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 IntraStent Unmounted Balloon Expandable Stent

Part 7. Keywords

a) Keywords:

IntraStent Unmounted Balloon Expandable Stent, ev3