

Notice Information: - Advisory
13 May 2011

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

Part 2. Target Audience

a) Target Audience:

Hospital Managers / CEOs
Risk Managers
Clinical Directors
Clinical Engineers
General Surgeons
Urological Surgeons
Gynaecological Surgeons
Gastrointestinal Surgeons
Gastroenterologists
Obstetricians
Endoscopy units
Theatre and Nursing Staff
Purchasing Managers
Nursing Managers
Emergency Departments
Hospital personnel
Medical device distributors

Part 3. Problem/Issue

a) Problem/Issue:

Stolen non-sterile Boston Scientific Endoscopy and Urology/Women's Health products are labelled as "Sterile".

Part 4. Background Information

a) Background Information:

Boston Scientific Corporation has issued an alert informing customers of a stolen shipment of several Endoscopy and Urology/Women's Health products. These devices were stolen while en route to the sterilisation facility sometime between April 8, 2011 and April 11, 2011. The pre-printed labels on these devices state that they are "Sterile"; however they were stolen prior to being sterilized and are non-sterile. Use of these non-sterile devices may lead to infection.

It is not known if the products have left or will leave the USA. As a precautionary measure, Boston Scientific will be informing its customers worldwide about the issue.

Only specific UPNs (Material/Catalog Number) and Batches identified in the table below are affected.

Part 5. Action to be taken

a) Action to be taken:

The IMB advises that you:

- Check your inventory for the affected product
- Monitor all incoming shipments for the affected product
- If you have any of these identified devices in your current inventory or receive any future delivery of these batches of devices, do not use the devices and contact Boston Scientific
- If healthcare professionals suspect or know that the stolen non-sterile devices have been used, it is recommended that they monitor and treat patients accordingly.

Part 6. Enquiries

- a) All enquiries should be made to:

If you have any enquiries relating to the above you may contact the Medical Devices Vigilance & Compliance section of the Human Products Monitoring Department of the Irish Medicines Board at the contact details listed below.

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

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Enquiries to the manufacturer should be addressed to:

Boston Scientific Ltd

Breakspear Park

Breakspear Way

Hemel Hempstead

Herts HP2 4TZ

Contact person: Cait Gatt Telephone: +44 1442 411673 Fax: +44 1442 411816

Contact person: Cait Gatt

Telephone: +44 1442 411673

Fax: +44 1442 411816

E-mail: Cait.Gatt@bsci.com

[Click here to download a PDF version of the Safety Notice](#)