IRISH MEDICINES BOARD
SAFETY NOTICE

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Non-sterile Boston Scientific Endoscopy and Urology / Women's Health Devices Stolen

IMB Safety Notice: SN2011(08)
Circulation Date: 13 May 2011

MANUFACTURER:
Boston Scientific Corporation

TARGET GROUPS
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

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

BACKGROUND
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.

SAFETY NOTICE

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.

Device Name	Material/UPN/ Catalog Number	Lot/Batch Number	Device Description	Expiration date	Class / GMDN code
Resolution™ II; 155cm Box 20	M00522502	ML00000042	Clipping device used for placement in the gastro-intestinal (GI) tract for hemostasis, endoscopic marking, anchoring jejunal feeding tubes or as a supplementary method for closure of GI tract luminal perforations.	31 Mar 2012	IIb / 35649
Resolution™ II; 235cm Box 10	M00522511	ML00000043			
Resolution™ II; 235cm Box 20	M00522512	ML00000040			
Resolution Clip™; 235cm (single unit)	M00522610	ML000019C2	Clipping device used for placement in the gastro-intestinal (GI) tract for hemostasis, endoscopic marking, anchoring jejunal feeding tubes or as a supplementary method for closure of GI tract luminal perforations.	31 Mar 2014	IIb / 35649
Resolution Clip™; 235cm Box 10	M00522611	ML000017C2			
Resolution Clip™; 235cm Box 10	M00522611	ML000018C2			
Resolution Clip™; 235cm Box 20	M00522612	ML000020C2			
Pinnacle™ Pelvic Floor Repair Kit	M0068317050	ML00000034	Pelvic Floor Repair Kit: Kits used for Pelvic Floor Repair of Pelvic Organ Prolapse	31 Mar 2014	IIb / 45034
Flexiva™ 365 High Power Single-Use Laser Fiber; Box 5	M0068403921	ML00000046	Fiber optic laser energy delivery devices	30 Apr 2012	not CE - marked
Flexiva™ 550 High Power Single-Use Laser Fiber	M0068403930	ML00000060			
Flexiva™ 1000 High Power Single-Use Laser Fiber	M0068403940	ML00000048			
AccuMax ™ 365 Single-Use Holmium Laser Fiber	M0068404020	ML00000061	Fiber optic laser energy delivery devices	30 Apr 2014	IIb / 36185
Advantage™ System (single unit)	M0068502000	ML00000035	Implantable mesh slings used for stress urinary incontinence	31 Mar 2014	IIb / 45034
Advantage™ System Box 5	M006850200051	ML00000036			
Advantage Fit™ System Box 5	M0068502111	ML00000038			

ACTIONS OR RECOMMENDATIONS

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.

ENQUIRIES

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

SAFETY NOTICE

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
Website: www.imb.ie

Enquiries to the manufacturer should be addressed to:

Boston Scientific Ltd
Breakspear Park
Breakspear Way
Hemel Hempstad
Herts HP2 4TZ

Contact person: Cait Gatt
Telephone: +44 1442 411673
Fax: +44 1442 411816
E-mail: Cait.Gatt@bsci.com