

Medical Device Alert

Ref: MDA/2011/062 Issued: 06 June 2011 at 14:00

Device

Resolution™ II Clip
 Pinnacle™ Pelvic Floor Repair Kit
 Flexiva 365™ High Power Single-Use Laser Fiber
 Flexiva 550™ High Power Single-Use Laser Fiber
 Flexiva 1000™ High Power Single-Use Laser Fiber
 AccuMax™ 365 Single-Use Holmium Laser Fiber
 Advantage™ Transvaginal Mid-Urethral Sling System
 Advantage Fit™ System

Manufactured by Boston Scientific

Specific Material/UPN and Lot numbers – see Appendix

Problem	Action
<p>The manufacturer issued a Field Safety Notice (FSN) on 10 May 2011 for these devices that were stolen before they were sterilized, although labelled as 'sterile'.</p> <p>A copy of the FSN is in the appendix of this alert, and it is also available on the MHRA website.</p> <p>This alert has been issued in support of the manufacturer's actions.</p>	<ul style="list-style-type: none"> • Ensure that relevant members of staff are aware of the problem. • Carry out the actions described in the manufacturer's FSN, including vigilance related to any suspicious transactions with these devices. • If you discover any of these stolen products in the UK report it to the MHRA Devices Compliance Unit via email: devices.compliance@mhra.gsi.gov.uk
Action by	
<p>All those who use these endoscopy, urology and women's health devices; suppliers; distributors and purchasers.</p>	
CAS deadlines	Contact
<p>Action underway: 20 June 2011</p> <p>Action complete: 04 July 2011</p>	<p>Manufacturer Cait Gatt Boston Scientific Ltd Tel: 01442 411 673 Email: Cait.Gatt@bsci.com</p>

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Clinical governance leads
- Day surgery units
- Endoscopy units
- Gastroenterology departments
- Gastroenterology, directors of
- Gastro-intestinal surgeons
- Gynaecologists
- Medical directors
- Purchasing managers
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of
- Urology departments

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Hospitals in the independent sector
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer

Cait Gatt
Boston Scientific Ltd
Breakspear Park
Breakspear Way
Hemel Hempstead
HP2 4TZ

Tel: 01442 411 673

Fax: 01442 411 816

Email: Cait.Gatt@bsci.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/062** or **2011/005/006/291/001**

Technical aspects

Mrs Sally Mounter
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7168

Fax: 020 8754 3965

Email: sally.mounter@mhra.gsi.gov.uk

Clinical aspects

Dr Nicola Lennard
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7126

Fax: 020 8754 3965

Email: nicola.lennard@mhra.gsi.gov.uk

Compliance aspects

Medicines & Healthcare products Regulatory Agency
Floor 5
151 Buckingham Palace Road
London SW1W 9SZ
Email: devices.compliance@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: nss.irc@nhs.net

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

MHRA is an executive agency of the Department of Health

© Crown Copyright 2011

Addressees may take copies for distribution within their own organisations

Appendix



Boston Scientific International S.A.
 European Headquarters – Paris
 55, Avenue des Champs Pierreux
 TSA 51101
 92729 Nanterre Cedex
 France

Tel. 33 (0)1 57 66 80 00
 Fax 33 (0)1 57 66 84 99
www.bostonscientific.com

«Sold_to» - CP

«Hospital_Name»
 «Users_Name» - «Department»
 «Customer_Address»
 «Zip_Code» «City» - «Country_name»

Reference: 90677986-FA

May 10, 2011

Field Safety Notice
Notification URGENT: Risk of Infection
Non-Sterile Boston Scientific Devices Stolen
Endoscopy and Urology / Women’s Health Devices

Dear «Users_Name»,

Boston Scientific Corporation is alerting you about a stolen shipment of Endoscopy and Urology / Women’s Health medical devices. **These devices were stolen while en route to our sterilization facility sometime between April 8, 2011 and April 11, 2011.**

The 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.

Required Actions

- Check your inventory for affected product
- Segregate
- Monitor all incoming shipments for affected product

It is recommended that health care professionals monitor and treat patients for adverse events, such as post-operative infection, if they suspect or know that the below stolen non-sterile devices have been used.

If you have any of these identified devices in your current inventory or receive any future delivery of these batches of devices, **please do not use the devices** and contact your local office at Cas Sherrard – Tel: 01442 411731.

Please visit our website at BostonScientific.com for information on device labeling, device photos and other additional information concerning this issue.

The table below provides a complete list of all affected products, including Product Description, Material Number (UPN) and Lot/Batch numbers. **Please note that only the material listed in the table below is affected. No other Boston Scientific product is involved by this Field Safety Notice.**

Device Name	Product Description	Material/UPN/	Lot/Batch #
Resolution™ II; 155cm Box 20	Clipping device used for placement in the gastrointestinal (GI) tract for hemostasis, endoscopic marking, anchoring jejunal feeding tubes or as a	M00522502	ML00000042
Resolution™ II; 235cm Box 10		M00522511	ML00000043
Resolution™ II; 235cm Box 20		M00522512	ML00000040
Resolution Clip™; 235cm Single unit		M00522610	ML000019C2
Resolution Clip™; 235cm Box 10		M00522611	ML000017C2

- Page 1 of 2 -

«Sold_to» - CP

Resolution Clip™; 235cm Box 10	supplementary method for closure of GI tract luminal perforations.	M00522611	ML000018C2
Resolution Clip™; 235cm Box 20		M00522612	ML000020C2
Pinnacle™ Pelvic Floor Repair Kit	Pelvic Floor Repair Kit: Kits used for Pelvic Floor Repair of Pelvic Organ Prolapse	M0068317050	ML00000034
Flexiva™ 365 High Power Single-Use Laser Fiber; Box 5	Fiber optic laser energy delivery devices	M0068403921	ML00000046
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
Advantage™ System Single unit	Implantable mesh slings used for stress urinary incontinence	M0068502000	ML00000035
Advantage™ System Box 5		M00685020005 1	ML00000036
Advantage Fit™ System Box 5		M0068502111	ML00000038

Boston Scientific Corporation is working with the U.S. Food and Drug Administration and law enforcement officials to recover this stolen shipment.

Your vigilance related to any suspicious transactions relating to the devices listed above is greatly appreciated. For example unusually low pricing may be an indication that the product has been stolen.

Anyone who has information regarding this incident or has received suspicious or unsolicited offers for the devices identified above, after the date of the theft, is encouraged to contact their Boston Scientific local offices at Cas Sherrard – Tel: 01442 411731.

Please pass on this notice to any health professional of your organization that need to be aware and to any organization where the potentially affected devices have been transferred (if appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Your Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local office (Cas Sherrard – Tel: 01442 411731).

Yours sincerely,

Marie Pierre Barlangua
 Quality Department
 Boston Scientific International S.A