Medical Device Alert

Ref: MDA/2012/064 Issued: 12 September 2012 at 15:00

Device

Surgical stapler.
Duet TRS™ Universal straight and articulating single use loading units (SULU)

These devices may also have been incorporated into BEST PRACTICE™ kits.

Manufactured by Covidien.

Problem

These tissue-reinforced stapler loading units have the potential to injure adjacent anatomical structures within the thorax and abdomen, which may result in life-threatening post-operative complications.

This alert extends the actions in a previous Medical Device Alert, MDA/2012/005.

Covidien has issued an urgent product recall (Field Safety Notice dated 22 August 2012) and has discontinued manufacturing these loading units.

Action by

All surgeons and surgical staff involved in the use of these devices.

Action

- Immediately quarantine and stop using these devices.
- Return any products to the manufacturer, following the instructions in the manufacturer's Field Safety Notice (FSN).

CAS deadlines

Action underway: 19 September 2012

Action complete: 26 September 2012

Contact

Manufacturer
Amanda Woolven
Covidien Commercial (UK) Ltd

Tel: 01329 224 435
Fax: 01329 224 418
Email: Amanda.woolven@covidien.com

Device

The affected product codes and descriptions are:

Product code	Description	Lot/serial number	Manufacturing/distribution dates
DUET4535	Duet TRS™ 45 3.5mm straight SULU	All	All
DUET4535A	Duet TRS™ 45 3.5mm articulating SULU	All	All
DUET4548	Duet TRS™ 45 4.8mm straight SULU	All	All
DUET4548A	Duet TRS™ 45 4.8mm articulating SULU	All	All
DUET6035	Duet TRS™ 60 3.5mm straight SULU	All	All
DUET6035A	Duet TRS™ 60 3.5mm articulating SULU	All	All
DUET6048	Duet TRS™ 60 4.8mm straight SULU	All	All
DUET6048A	Duet TRS™ 60 4.8mm articulating SULU	All	All

Units from the affected lots may also have been incorporated into Covidien BEST PRACTICE™ kits.
The UK code for the affected kits is KIT1003 (K) Imperial Sleeve Kit

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)
- 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:

- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Clinical governance leads
- Directors of nursing
- General surgeons
- General surgery
- General surgical units, directors of
- Medical directors
- Nursing director
- Paediatric surgeons
- Paediatric surgery, directors of
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Thoracic surgeons
- Thoracic surgery departments
- Thoracic surgery directors
- Transplant surgeons
- Urological surgeons

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
This alert should be read by:
- Hospitals in the independent sector
- Independent treatment centres

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
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Hampshire
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Tel: 01329 224 435
Fax: 01329 224 418

Email: Amanda.woolven@covidien.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/064** or **2012/001/016/081/009**

Technical aspects
Sally Mounter / Annie Dhillon
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Clinical aspects
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Medicines & Healthcare products Regulatory Agency
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Email: nicola.lennard@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.iric@nhs.net

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

Wales

Enquiries in Wales should be addressed to:
Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

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