

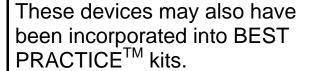
Medical Device Alert

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

Device

Surgical stapler.

Duet TRSTM Universal straight and articulating single use loading units (SULU)



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

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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

Amanda Woolven Covidien Commercial (UK) Ltd 4500 Parkway Whiteley Hampshire PO15 7NY

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

Tel: 020 3080 7168 / 6886

Fax: 020 8754 3965

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

annie.dhillon@mhra.gsi.gov.uk

Clinical aspects

Nicola Lennard Medicines & Healthcare products Regulatory Agency Floor 151 Buckingham Palace Road

Tel: 020 3080 7126 Fax: 020 8754 3965

London SW1W 9SZ

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

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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

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

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