MDA/2018/28(Wales)

Medical Device Alert

Llywodraeth Cymru
Welsh Government

07 August 2018

Parc Cathays
Caerdydd CF10 3NQ

Cathays Park
Cardiff CF10 3NQ

Orthopaedic bone plates and cortical screws: ADVANSYS MLP-DLP; ADVANSYS TTC; Large QWIX; TIBIAXYS and UNI-CP–Sterile – Risk of infection

1. Identify and quarantine all affected devices.
2. Follow actions recommended in the manufacturer's Field Safety Notice.
3. Complete the certificate of acknowledgment attached to the Field Safety Notice and return it to the manufacturer.
4. Report all adverse events involving this device to Newdeal SAS and the MHRA or the appropriate Devolved Administration.

Sent to:
NHS Wales Shared Services Partnership
Directors of Public Health,
Chief Executives, NHS Trusts
Chief Executives, LHBs
Medical Directors, NHS Trusts
Nurse Directors, LHBs
Executive Nurses, NHS Trusts
NHS Direct
CSSIW
Social Services
HIW

A list of people who need to have early sight of this information is given in the Notice.
This Notice has been endorsed by the Welsh Government as being relevant to NHS Wales.

Points of particular importance in Wales:

Healthcare Quality Division
Welsh Government
Cathays Park
Cardiff CF10 3NQ

This document is available online at:
https://www2.nphs.wales.nhs.uk/contacts.nsf

Ffôn/Tel: 029 2082 3624/029 2082 5510
Ebost/Email: Haz-Aic@wales.gsi.gov.uk

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/028 Issued: 01 August 2018 at 14:00 Valid until: August 2019

Orthopaedic bone plates and cortical screws: ADVANSYS MLP-DLP; ADVANSYS TTC; Large QWIX; TIBIAXYS and UNI-CP–Sterile – Risk of infection

Summary

Manufactured by Newdeal SAS – Risk of infection from compromised packaging.

Action

1. Identify and quarantine all affected devices.
2. Follow actions recommended in the manufacturer's Field Safety Notice.
3. Complete the certificate of acknowledgment attached to the Field Safety Notice and return it to the manufacturer.
4. Report all adverse events involving this device to Newdeal SAS and the MHRA or the appropriate Devolved Administration.

Action by
All users of the affected medical device.

Deadlines for actions
Actions underway: 15 August 2018
Actions complete: 29 August 2018

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

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Device details

The affected devices are used in various bone and joint reconstruction procedures.

In addition to the Field Safety Notice which details affected product, please refer to the spreadsheet which accompanies this MDA for additional unique device identification information.

Problem / background

In May 2018, Newdeal SAS, a company within Integra LifeSciences Group, issued a Field Safety Notice informing distributors and clinicians of devices possibly affected with defective packaging. This defect may result in insufficient sealing, a potential consequence of which is an increased risk of infection.

This Medical Device Alert is being issued to ensure that all hospitals are aware of the issue and that adequate action is taken to mitigate potential risk to patients.

Manufacturer contacts

Newdeal SAS
Tel: +33 (0)4 37 47 51 51
Email: emea-fsca-recon@integralife.com or marilyse.latour@integralife.com
Fax/telecopy: +33 (0)4 37 47 59 30

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- Orthopaedic surgeons
- Sterile services departments
- Supplies managers
- Theatre managers
- Theatres

Independent distribution

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

- 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 Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/028** or **2018/005/025/291/009**.

Technical aspects
Hasan Samee-Ahmed, MHRA
Tel: 020 3080 6807
Email: hasan.samee-ahmed@mhra.gov.uk

Clinical aspects
Devices Clinical Team, MHRA
Tel: 020 3080 7274
Email: dct@mhra.gov.uk

Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland
Alerts in Northern Ireland are distributed via the NICAS system.
Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre, CMO Group,
Department of Health, Social Services and Public Safety
Tel: 028 9052 3868
Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

Reporting adverse incidents in Northern Ireland
Please report directly to NIAIC using the forms on our website.

Scotland
Enquiries and adverse incident reports in Scotland should be addressed to:
Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland
Tel: 0131 275 7575
Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland
NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.
Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.
Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales
Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government
Tel: 02920 823 624 / 02920 825 510
Email: Haz-Aic@wales.gsi.gov.uk

Reporting adverse incidents in Wales
Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).