



Llywodraeth Cymru
Welsh Government

Cathays Park
Cardiff CF10 3NQ

Medical Device Alert

10 October 2018

Parc Cathays
Caerdydd CF10 3NQ

Device: Various trauma guide wires – risk of infection due to packaging failure

- Locate, quarantine and return all affected product.
- Return acknowledgement document to manufacturer (or complete online form as stated in the Field Safety Notice (FSN)).

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**



Medical Device Alert

MDA/2018/032

Issued: 24 September 2018 at 14:00

Valid until: September 2019

Various trauma guide wires – risk of infection due to packaging failure

Summary

Manufactured by Zimmer Biomet with expiry dates prior to 31 May 2028 – wire may breach packaging, compromising sterility of device.

Action

- Locate, quarantine and return all affected product.
- Return acknowledgement document to manufacturer (or complete online form as stated in the [Field Safety Notice \(FSN\)](#)).

Action by

All healthcare professional involved in the purchase and use devices

Deadlines for actions

Actions underway: 22 October 2018

Actions complete: 12 November 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.

Device details

Affected devices with expiry date prior to 31 May 2028:

Item Number	Item Description
469360	DRILL PT GUIDE WIRE 3.2MMX98CM
469340	DRILL PT GUIDE WIRE 2MM X 98CM
469320	DRILL PT GUIDE WIRE 2MM X 60CM
469060	BALL TIP GUIDE WIRE 3.2MMX98CM
469055	BALL TIP GUIDE WIRE 3.2MMX55CM
469040	GUIDE WIRE w/ BALL TIP 2.0MMX98CM
469020	GUIDE WIRE w/ BALL TIP 2.0MMX60CM
467265	GUIDE PIN 2.8BL & 3.2PL 60CM (L) PK/2
467260	GUIDE PIN 2.8BL & 3.2PL 98CM (L) PK/2
467220	NL DRIVING GUIDE 4.4MM X 80CM
29402	BEAD TIP GD WIRE 3.0MM X 60CM
14-443053	3.2MM X 510MM COCR THD TIP WIRE
14-443023	RECON DRILL 6MM X 439MM SMALL STATURE
14-441053	3.2MM X 560MM COCR THD TIP WIRE

Manufacturer contacts

Zimmer Biomet
 Red Dragon Court, Unit 2, South Road
 Bridgend Industrial Estate
 Bridgend
 South Wales
 CF13 3PT

Tel: 01656 333932

Email: fieldaction.uk@zimmerbiomet.com

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:

- Infection control departments
- Infection control nurses
- Infection prevention and control directors
- Microbiologists
- Orthopaedic surgeons
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Public Health England

Directors for onward distribution to:

- Collaborating centres
- Consultants in communicable disease control
- Divisional directors
- Heads of department
- Heads of health, safety and quality
- Health protection nurses
- PHE laboratories
- Regional microbiologists
- Risk manager
- Safety officers

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/2018/032** or **2018/006/021/701/023**

Technical aspects

Sara Vincent or Catriona Blake, MHRA

Tel: 020 3080 7169 or 7219

Email: sara.vincent@mhra.gov.uk or catriona.blake@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.irc@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 \(Wales\)](#).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health and Social Care.

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