Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2017/022 Issued: 17 August 2017 at 14: 30 Valid until: August 2018

DePuy Synthes Impactor for PFNA (Proximal Femoral Nail Anti-rotation) Blade: risk of infection

Summary

Manufactured by Synthes GmbH – Recall due to risk of infection from cracked weld of the handle.

Action

- Review your inventory to identify affected products
- Refer to the manufacturer's Field Safety Notice (dated April 2017) for alternative devices to use
- Report all adverse events involving this device to DePuy Synthes and the MHRA or the appropriate Devolved Administration.

Action by

- Medical directors
- Orthopaedic departments
- Orthopaedic and trauma surgeons
- Staff involved in the management of trauma patients

Deadlines for actions

Actions underway: 01 September 2017
Actions complete: 15 September 2017

NOTE: These deadlines are for systems to be in place to take actions and not for the completion of patient follow-up.

Department of Health An Roinn Sláinte Männystrie O Poustie www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

All lots of the DePuy Synthes Impactor for PFNA Blade (P/N 03.010.410) are affected.

Problem / background

In December 2016 DePuy Synthes issued a Field Safety Notice (FSN) informing clinicians of the possibility of breakage of the PFNA Blade impactor handle. If the breakage goes unnoticed, any body fluids that get into the handle during use would pose a risk of cross-contamination to other patients.

The manufacturer sent a second Field Safety Notice in April 2017 to hospitals that hadn't replied to the first FSN.

MHRA is issuing this Medical Device Alert to ensure that all hospitals are aware of the problem and that adequate action is taken to mitigate risks to patients.

Manufacturer contacts

Jody Cadd
Field Action Manager
Depuy Synthes GmbH
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Zuchwil
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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 SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Equipment stores
- Fracture clinics
- General surgeons
- General surgery
- General surgical units, directors of
- Orthopaedic surgeons
- Sterile services departments
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Independent distribution

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

- Hospitals in the independent sector

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.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2017/022** or **2016/012/012/291/031**

Technical aspects

Jacques Pouget or Michelle Kelly, MHRA

Tel: 020 3080 6143 and 020 3080 7145

Email: jacques.pouget@mhra.gov.uk or michelle.kelly@mhra.gov.uk

Clinical aspects

Device 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
Fax: 0131 314 0722

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).