



Medical Device Alert

MDA/2020/020

Issued: 10 July 2020 at 10:30

Spinal fixation system – risk of implant failure prior to completion of bone healing

Summary

Manufactured by Synthes GmbH – cracking of the USS II Polyaxial 3D Head rings may result in loosening of the fixation system prior to completion of bone healing.

Action

Note: This is a targeted Medical Device Alert sent to trusts supplied with affected devices.

Affected trusts will receive this alert via the Central Alerting System (CAS).

- Identify and quarantine all affected devices within 2 weeks of receiving this MDA (see Device details section below and attached spreadsheet).
- Follow the actions recommended in the manufacturer's [Field Safety Notice](#).
- Follow up patients implanted with affected devices.

MHRA has sought expert clinical advice that recommends all patients receive the following additional follow-up to identify implant failure:

- > All patients who have had the device implanted for less than 2 years should be contacted within 3 months to discuss if the patient has symptoms which may indicate implant failure.
 - > If the patient does **not** have symptoms, they should be reviewed annually for symptoms for a minimum of 2 years after the date of implantation.
 - > If symptoms are present which may indicate implant failure, medical imaging such as X-ray / CT* can be used to confirm this. Treatment options should be explored using clinical judgement and conversation with the patient.
The patient should be reviewed annually for up to 5 years.
- Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: [England](#), [Scotland](#), [Northern Ireland](#), [Wales](#). You should also report directly to manufacturers if your local or national systems do not.

*In all cases, the benefit of ionising radiation screening should be weighed against the risks from radiation exposure on an individual patient basis, in line with the requirements of The Ionising Radiation (Medical Exposure) Regulations 2017.

Action by

- Orthopaedic spinal surgeons
- Paediatric spinal surgeons
- Supplies managers
- Theatre managers

Deadlines for actions

Actions underway: 24 July 2020

Actions complete: 02 October 2020

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

This is a batch related issue and not all devices are affected. Details of the affected product and batch numbers can be found in the manufacturer's [Field Safety Notice](#) and the spreadsheet which accompanies this MDA.

Problem / background

The manufacturer issued a [Field Safety Notice](#) dated 13 November 2019 to inform users of the potential of intra-operative or post-operative cracking of the USS II Polyaxial 3D Head rings, which may result in loosening of the rods, poor spinal mechanics, non-union or malunion, pain or dislocation.

The manufacturer reports that the majority of implant failures have occurred and been identified during the procedure.

However, there is the potential for cracking to occur and / or be identified post-operatively. Therefore, the aim of this MDA is to provide additional guidance on the clinical follow-up of patients implanted with affected devices.

Manufacturer contacts

Synthes GmbH

Tel: +44 113 387 6261

Email: MDFieldActionsUKIrl@its.jnj.com

Distribution

This is a targeted MDA sent to trusts supplied with these devices.

Affected trusts will receive this alert via the Central Alerting System (CAS).

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:

- Fracture clinics
- Health and safety managers

- Medical directors
- Operating department practitioners
- Orthopaedic surgeons
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric nurse specialists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Radiology departments
- Radiology directors
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Independent distribution

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

- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

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/2020/020 or 2019/011/013/291/013.

Technical aspects

Devices Safety and Surveillance Group, MHRA

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the [Yellow Card reporting page](#)

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the [forms on the website](#).

Alerts in Northern Ireland are distributed via the [NICAS system](#).

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.irc@nhs.net

To report an adverse incident involving a medical device in Scotland, [email IRIC](#) to request a webform account.

For more information, or if you can't access the webform, visit the website: [how to report an adverse incident](#)

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 255278 or 03000 255510

Email: Haz-Aic@gov.wales

To report an adverse incident involving a medical device in Wales, use the [Yellow Card reporting page](#) 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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