Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/010 Issued: 18 March 2020 at 14:00

Spinal implant: MAGEC System Model X rods – risk of failure in use

Summary

Manufactured by NuVasive Inc. – risk of end cap separation after implantation.

Action

- Identify and quarantine all affected devices (see details below).
- Follow actions recommended in the manufacturer's Field Safety Notice (FSN).
- Ensure systems are in place to 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 end cap separation:

  - Anteroposterior X-ray imaging within 3 months of this alert.*
  - Advise all patients about the possible complications resulting from this issue as described in the manufacturer's FSN and what alternative treatment options are available. Each patient should be assessed individually using your own clinical judgement.
  - Continue patient monitoring in alignment with the manufacturer's instructions for use **using anteroposterior X-ray imaging** instead of ultrasound imaging.

- 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

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Deadlines for actions
Actions underway: 17/04/2020
Actions complete: 10/06/2020

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

In addition to the manufacturer's FSN, which details lot numbers of affected products, please refer to the table below. All the products identified in the table were marketed as MAGEC Model X rods.

Device identifier GTIN	Catalogue number (manufacturer product code)	Product description
00812258022624	PA0684-001	MAGEC 2 Rod, 4.5mm 90mm Standard
00812258022662	PA0684-002	MAGEC 2 Rod, 5.5mm 90mm Standard
00812258022631	PA0684-003	MAGEC 2 Rod, 6.0mm 90mm Standard
00812258022631	PA0684-004	MAGEC 2 Rod, 4.5mm 90mm Offset
00812258022679	PA0684-005	MAGEC 2 Rod, 5.5mm 90mm Offset
00812258022716	PA0684-006	MAGEC 2 Rod, 6.0mm 90mm Offset
00812258022600	PA0684-007	MAGEC 2 Rod, 4.5mm 70mm Standard
00812258022648	PA0684-008	MAGEC 2 Rod, 5.5mm 70mm Standard
00812258022686	PA0684-009	MAGEC 2 Rod, 6.0mm 70mm Standard
00812258022617	PA0684-010	MAGEC 2 Rod, 4.5mm 70mm Offset
00812258022655	PA0684-011	MAGEC 2 Rod, 5.5mm 70mm Offset
00812258022693	PA0684-012	MAGEC 2 Rod, 6.0mm 70mm Offset
00812258029265	PA0684-013	MAGEC 2 Rod, 5.0mm 90mm Standard
00812258029272	PA0684-014	MAGEC 2 Rod, 5.0mm 90mm Offset
00812258029296	PA0684-015	MAGEC 2 Rod, 5.0mm 70mm Standard
00812258029289	PA0684-016	MAGEC 2 Rod, 5.0mm 70mm Offset

Problem / background

The manufacturer issued a Field Safety Notice, dated 13 February 2020, to inform users of the potential for the end cap component of affected devices to separate from the housing tube after implantation. The end cap is a threaded component which is designed to prevent the ingress and egress of fluid from the mechanism of the MAGEC System. This component may de-thread after implantation, exposing internal components of the actuator. This could lead to accelerated degeneration of the mechanism and release of titanium alloy wear debris. This issue affects only the MAGEC Model X device generation.

The manufacturer says that affected devices might still distract and/or continue serving as an internal brace despite separation of the end cap. However, the aim of this MDA is to provide additional guidance on the clinical follow-up of patients implanted with affected devices.

Manufacturer contacts

Name of manufacturer: Nuvasive Specialized Orthopedics
Tel: +1 858-909-1800
Email: FSNMAGEC@nuvasive.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:

- 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
- Radiographer superintendents
- Radiographers
- Radiologists
- 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/2020/010 or 2020/002/018/291/002.

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.iric@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).