Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/011 Issued: 01 April 2020 at 14:00

Spinal implant: All MAGEC Systems – supply suspended to the UK

Summary

Manufactured by NuVasive Specialized Orthopedics – supply of all MAGEC rods suspended to the UK market during a review by MHRA.

Action

- Do not implant MAGEC rods in the UK until further notice.
- Identify all patients implanted with a MAGEC System and ensure systems are in place to follow up these patients.

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

MAGEC Model X only:

- X-ray imaging within 3 months of 18 March 2020 as stated in MDA/2020/010.*

ALL MAGEC Systems:

- Advise all patients about the possible complications resulting from the failure of components as described in earlier Field Safety Notices (see problem/background section below) once implanted 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 X-ray imaging** instead of ultrasound imaging.

Due to the current COVID-19 healthcare crisis, we are aware follow-up and assessments may not take place within the current timescales and in the usual manner. Follow-up recommendations should be risk assessed and completed as soon as possible.

- Ensure that staff are aware of all the issues highlighted in the manufacturer's FSNs (see problem/background section below) and in MDA/2020/010.
- In the exceptionally rare case where the use of the device is deemed by the clinician to be essential, the MHRA will consider these on a case-by-case basis. Please contact AIC@mhra.gov.uk to request further information.
- 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.

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

* 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: 16 April 2020
Actions complete: 28 May 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.

Problem / background

NuVasive has undertaken voluntary action to suspend the supply of all MAGEC rods to the UK to address concerns identified by MHRA over the continued use of the device. This action is described in the Field Safety Notice issued by the manufacturer dated 01 April 2020.

MHRA issued a Medical Device Alert MDA/2020/010, dated 18 March 2020, which addressed the need for additional clinical follow-up in relation to the MAGEC Model X following the manufacturer's Field Safety Notice dated 13 February 2020.

The manufacturer has previously issued the following FSNs for problems such as locking pin breakage, O-ring seal failure, generation of metal wear debris, and failure of the rod to distract affecting other MAGEC generations:

1. Field Safety Notice - June 2019
2. Field Safety Notice - September 2014 (manufactured by Ellipse)

These failure modes may result in the need for the early removal of the device and inadequate treatment. However, at present we suggest assessing patients individually and we are not recommending prophylactic removal of the devices.

MHRA's responsibilities include ensuring that medical devices meet applicable standards of safety, quality and efficacy. One way in which we achieve this is by undertaking the continuous market surveillance of medical devices. MHRA has considered recent evidence about the MAGEC System, both published and unpublished, together with reported adverse incident data collected by all four UK health systems over time. MHRA is conducting a robust investigation to determine whether the benefits of these devices continue to outweigh the risks.

The supply of MAGEC Systems will continue to be suspended while the investigation is ongoing.

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/2020/011 or 2020/003/010/479/001**.

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).