MHRA Device Safety Information

Reference: MDSI2402 **Issued:** 13 March 2024 **Review Date:** 13 March 2025

NuVasive Specialized Orthopedics (NSO), MAGEC X System: UK suspension lifted

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 12 March 2024. The original webpage can be accessed here.

Summary

The MHRA has conducted a thorough assessment of technical and biological safety information provided by NSO and is satisfied that the modified MAGEC X system can now be used in the UK.

Action

The modified MAGEC X system can now be appropriately selected for use in surgery.

- Follow the actions set out in the manufacturers FSN
- The modified MAGEC X system should only be implanted in accordance with the manufacturer instructions for use.
- Incidents should be reported to local incident reporting and learning systems (Datix, Ullyses, InPhase) and to the Incident Reporting & Investigation Centre (IRIC)

Device details

Manufacturer name:	NuVasive Specialized Orthopedics (NSO)
Device name:	MAGnetic Expansion Control X (MAGEC X) system (orthopaedic spinal rod for use in skeletally immature patients less than 10 years of age)
Lot/serial numbers:	All MAGEC X systems

Background information

The MHRA has conducted a thorough assessment of technical and biological safety information provided by NSO and is satisfied that the modified MAGEC X system can now be used in the UK. NSO has agreed to meet a set of conditions to monitor the long-term safety and performance of the device.

All previous generations of the MAGEC system (MAGEC 1,1.5, 2B) remain suspended in the UK and should not be implanted.

Explanation of identified safety issue

In March 2020, at the request of the MHRA, NSO voluntarily suspended the supply of MAGEC systems to the UK, pending the outcome of an MHRA investigation. All MAGEC System devices were affected by the suspension and this was communicated via MDA/2020/011.

Background information continued

On 25 March 2021, the MAGEC CE certificate was suspended by their Notified Body. This was communicated via DSI/2021/007. The CE mark for the MAGEC systems was reinstated on 19 November 2021 and communicated by the manufacturers Field Safety Notice. However, the devices remained suspended in the UK whilst the MHRA conducted an extensive assessment of the MAGEC system of devices which addressed the following concerns:

1. Unknown long-term biological safety profile

During the MHRA investigation, the MAGEC system was found to have insufficient long-term biological safety information. NSO has now provided chemical analysis and biological testing data to address this information gap. It was concluded that the results were acceptable according to the intended use of the device.

The MHRA has requested NSO to conduct a post-market clinical follow up study to proactively monitor the risk of exposure to metal wear debris in patients in which these devices are implanted. The MHRA will continue to review and assess the safety of the device on an ongoing basis.

2: Technical and Early Device Failures

The manufacturer had previously issued a number of Field Safety Notices (FSN) regarding failures of the device including locking pin breakage, O-ring seal failure, generation of metal wear debris, and failure of the rod to distract. These failures resulted in the need for early removal of the device and inadequate treatment.

The CE mark for MAGEC was reinstated in November 2021, with a revised shorter duration of implantation in the instructions for use following a decision made by NSO to globally align product information. The MAGEC system should now be removed after an implantation time of no more than 2 years. Devices remaining in place after 2 years may increase the rate of adverse events or complications.

The modified MAGEC X device has an updated endcap design to reduce the risk of end-cap component separation and unintended exposure to the patient of the internal components of the device. The modified MAGEC X is the only MAGEC device that will be available for use on the UK market. Previous generations of the MAGEC System should not be implanted.

3. Intended Use of the MAGEC System

The MAGEC system must be used in accordance with the manufacturer's instructions for use.

- The MAGEC system is indicated for use in skeletally immature patients less than 10 years of age with severe progressive spinal deformities (e.g., Cobb angle of 30 degrees or more; thoracic spine height of less than 22 cm) associated with or at risk of Thoracic Insufficiency Syndrome (TIS). TIS is defined as the inability of the thorax to support normal respiration or lung growth.
- The device should be removed after implantation time of no more than 2 years.
- After 2 years implantation time, continued implantation may increase the rate of adverse events or complications.

NSO and the MHRA will continue to monitor the safety and performance of the device through post market surveillance including clinical follow up studies.

Information MHRA has provided to patients and carers

- If your child or dependent have been waiting for surgery during the period of the UK suspension of these devices, you should discuss the options available to them with their medical team. The use of a particular device will depend upon the clinical decision making for the patient.
- If your child or dependent has a device implanted and they experience any pain or other problems associated with the implant, please speak to your implanting surgeon/ hospital in the first instance.
- If your child or dependent is due to have the device implanted, you may be invited to participate in post-market clinical follow-up activities. MHRA strongly recommends patient involvement to ensure the safety and effectiveness of the device can continue to be stringently monitored.
- Report any suspected or actual adverse incidents to the MHRA using the Yellow Card scheme website.

Suggested onward distribution (may not include all affected departments)

Device Managers	Operating Departments	Orthopaedics	Risk Management
Health & Safety		Paediatrics	Supplies/Procurement

Stakeholder engagement

Stakeholders who received an advanced copy for review include:

- Spinal Expert Advisory Group
- British Orthopaedic Association
- Incident Reporting and Investigation Centre (IRIC), NHS National Services Scotland
- NHS England – National Patient Safety Team
- Representatives from the Welsh Government
- Department of Health Northern Ireland

Information about IRIC

Incident Reporting & Investigation Centre (IRIC), Facilities Division, NHSScotland Assure NHS National Services Scotland, Tel: 0131 275 7575, email: nss.iric@nhs.scot

Accessibility: Please contact us using the above details if you are blind or have a sight impairment and would like to request this alert in a more suitable format.

IRIC remit: general information about adverse incidents, safety alerts and IRIC's role can be found in CEL 43 (2009), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities,* issued 30 October 2009.

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