Medicines & Healthcare products Regulatory Agency

Device Safety Information (DSI)

MAGEC X System, NuVasive Specialized Orthopedics (NSO): UK suspension lifted, DSI/2024/002

Devices Details

Device Name: MAGnetic Expansion Control X (MAGEC X) system (orthopaedic spinal rod for use in skeletally immature patients less than 10 years of age)

Affected lot numbers/serial numbers: All MAGEC X systems

Manufactured by: NuVasive Specialized Orthopedics (NSO)

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.

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.

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.

Actions

Actions for healthcare professionals

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.
- There are specific reporting arrangements for healthcare professionals to follow in each region. Healthcare professionals should report incidents:
  - in England and Wales to the Yellow Card scheme or via the Yellow Card app
  - in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
  - in Northern Ireland to the Northern Ireland Adverse Incident Centre and their local incident recording system

Actions for 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.

Additional information

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

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