MHRA Device Safety Information

MDSI (SC) 21/06 10 May 2021

Investigation update: CE mark suspended for all MAGEC systems manufactured by NuVasive Specialized Orthopedics, Inc.

Summary

MHRA has issued updated advice regarding the status of NuVasive Specialized Orthopedics, Inc. (NSO) MAGEC systems to the UK.

Background

In March 2020, NuVasive Specialized Orthopedics, Inc. (NSO) voluntarily suspended the supply of MAGEC systems to the UK. This was on the request of the MHRA, pending the outcome of an MHRA investigation. This was communicated by the MHRA's Medical Device Alert and a Field Safety Notice (FSN) issued by NSO on 01 April 2020.

The MHRA's investigation has identified several deficiencies with the technical documentation relating to MAGEC systems and NSO's quality management system. The MHRA sent its initial findings to NSO and their EU Notified Body in September 2020. Following this report, the Notified Body undertook its own review, which resulted in the CE certificate being suspended on 25 March 2021. Additional details on MHRA's investigation will be communicated in due course.

The MHRA, in consultation with its independent Spinal Expert Advisory Group, has continued to monitor the safety and performance of the MAGEC system. MHRA recognises that there are additional uncertainties stemming from the suspension of the CE certificate and, following feedback from the clinical community, we have updated our recommendations for clinicians.

Action

1. This notice should be brought to the attention of all appropriate managers and staff.
2. Refer to the attached MHRA targeted letter TL/2021/06 for a full list of actions

Enquiries and further information

Enquiries (and adverse incident reports) in Scotland should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

Reporting options are available on the HFS website: How to report an Adverse Incident

Further information about reporting incidents can be found in CEL 43 (2009) or by contacting IRIC at the above address.

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

06 May 2021

MHRA Reference: TL/2021/06

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MHRA's recommendations

- Do not implant MAGEC rods in the UK until further notice.
- Identify all patients who currently have a MAGEC System implanted and inform them, and their families, of the contents of this letter.
- Consult the IFU throughout the patient's treatment with the MAGEC system.
- Ensure systems are in place to follow up patients who have the device implanted. Continue to undertake follow-up of all patients according to normal clinical practice. Users should follow the appropriate postoperative procedure to assess the MAGEC System by X-ray imaging* whenever the device is adjusted or at a minimum of once every six months. The most recent images should be compared to immediate post-operative images to help identify signs of device failure, including component fracture or migration.

- Where removal will not cause additional harm:
    - If a component of the device is found to be broken, remove the device as soon as possible (Priority 3 under the current clinical guide to surgical prioritisation).
    - Check to make sure the rod is still distracting and if it is not, remove it as soon as possible (Priority 3 under the current clinical guide to surgical prioritisation).
    - Remove the device at the end of the distraction treatment and do not use it as a brace unless there is a specific medical reason to do so.
- Where the rod is intact and still functioning, continue to monitor.
- Report any suspected or actual adverse incidents involving these devices through your healthcare institution's local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales.
- Ensure clinicians are aware of the content of this letter and the previous safety communications issued about the system (ordered by date):
    > NSO Company Statement (05 April 2021).
    > NSO Field Safety Notice (11 December 2020). This was not distributed in the UK.
    > MHRA Medical Device Alert (MDA/2020/011) and NSO Field Safety Notice (01 April 2020).
    > NSO Field Safety Notice (13 February 2020) and MHRA Medical Device Alert (MDA/2020/010) (18 March 2020).
    > NSO Field Safety Notice (25 June 2019).
    > Ellipse Technologies Field Safety Notice (September 2014).

*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.

Exceptional use applications

At present, the MHRA has not had sight of the Notified Body's assessment that led to the suspension of the CE certificate, or the manufacturer's proposed corrective actions. Without this information, the uncertainties about the device cannot be fully assessed when considering applications for exceptional use. Therefore, the MHRA will not accept any further applications for exceptional use.

If CE certification is reinstated and the MHRA has been able to review the Notified Body's assessment, including the manufacturer's corrective action plan, we will reconsider this position.

Background information on CE certificate suspension

On 25 March 2021 NSO informed the MHRA that their CE certification for the MAGEC system had been suspended by their EU Notified Body.

By way of background, Notified Bodies are independent organisations designated by an EU Member State to undertake pre-market assessments to ensure that manufacturers, and their medical devices, meet the requirements of the legislation. Only then does the Notified Body issue a CE certificate, which in turn allows a manufacturer to place a CE mark on their device.

At present the UK continues to recognise CE marked medical devices and will do so until 30 June 2023. Therefore, providing a medical device has been CE marked, this medical device can continue to be used in the UK.

In cases where non-conformities with the regulations or safety issues with the device become evident, the Notified Body may suspend or withdraw a CE certificate. Suspension or withdrawal of a CE certificate prevents the device being placed on the market in the EU and UK.

The MHRA continues to work closely with the independent Spinal Expert Advisory Group and representatives of the specialty to provide supplementary information to support patients and clinicians, which we anticipate will be published soon.

Devices Safety and Surveillance Group
Medicines and Healthcare products Regulatory Agency
aic@mhra.gov.uk quoting ref TL/2021/06
gov.uk/mhra