URGENT FIELD SAFETY NOTICE / MAGEC® SYSTEM

DATE: 1 April 2020

COMMERCIAL NAME: **MAGEC® System**

TYPE OF ACTION: Advisory Notice

MAGEC® System

NuVasive, Inc. voluntarily issues this Urgent Field Safety Notice (FSN) to inform healthcare providers in the United Kingdom (UK) and Republic of Ireland (ROI) of the following information.

Description of the Issue:

The MAGEC® System is used to brace the spine during growth to minimize the progression of scoliosis. The MAGEC System is a metallic implant. The instructions for use (IFU) of the MAGEC System indicate that metallic implants can loosen, fracture, corrode, migrate, or cause pain. Consistent with the IFU and per the prior communication, this can manifest in vivo as locking pin breakage, O-ring seal failure, generation of metal wear debris, and failure of the rod to distract. Also, localized tissue discoloration may result from the use of the MAGEC rod, and patients with metal allergies and sensitivities are contraindicated for use with the MAGEC System.

While the MAGEC System remains CE marked, the MHRA and HPRA, as appropriate, are undertaking a market surveillance review of the MAGEC System. We have agreed to and respect the process, and are working with the MHRA and HPRA to that end.

While these discussions and this review is ongoing, no MAGEC System rods of any model number shall be implanted in the United Kingdom or Republic of Ireland until further notice. In the rare case where the use of the device is deemed by the clinician to be essential, the Competent Authority will consider these on a case-by-case basis. Please contact AIC@mhra.gov.uk in the UK or devices@hpra.ie in the ROI to request further information.

This policy will remain in place while the MHRA and HPRA complete the market surveillance review.

Clinical Impact:

As a result, there will be existing and prospective MAGEC patients in the UK and ROI who are impacted by the FSN. These patients include those who currently have an implanted MAGEC rod(s) who may need to undergo a removal/revision surgery for a myriad of reasons (e.g., end of useful life; full distraction achieved; infection; hardware failure; rod fracture). Similarly, there may be patients suffering from a medical condition (e.g., early onset scoliosis associated with or at risk of thoracic insufficiency syndrome) who are deemed suitable candidates by their clinician for the MAGEC System, and who therefore seek to have MAGEC rods implanted for the first time. Under either scenario, a clinician and/or patient may desire the implantation of a MAGEC rod or rods.

As with prior notices, NuVasive reiterates that it does not recommend a prophylactic removal of a functioning rod, and any decision of that nature should be made by the consulting surgeon in conjunction with the patient/family. Moreover, this FSN is not intended to signify a new or enhanced safety issue relating to the MAGEC System has been identified, or to otherwise suggest that patients with implanted rods are at an increased risk. Rather, the purpose of this FSN is to supplement the prior notice issued on February 13, 2020 with additional guidance regarding future implantation of any MAGEC rod in the UK and ROI.

NuVasive will work with each surgeon on a case-by-case basis with any questions, support, or clarity it can provide.

Recommended User Action:

- Do not implant MAGEC rods in the United Kingdom or Republic of Ireland until further notice. In the exceptionally rare case where the use of the device is deemed by the clinician to be essential, the MHRA or HPRA will consider these on a case-by-case basis. Please contact AIC@mhra.gov.uk in the UK or devices@hpra.ie in the ROI to request further information.
- The company will provide information necessary and facilitate this process for applicable case review and should be contacted as soon as possible prior to any intended cases at FSNMAGEC@nuvasive.com.
- Patients and/or families should be reminded of the importance of following the postoperative care instructions in the IFU.
- Forward this notice to anyone in your facility that needs to be informed.
- Review, complete, sign and return the attached Consignee Confirmation Form accompanying this notification in accordance with the directions on the form.
- Direct any additional manufacturer inquiries to FSNMAGEC@nuvasive.com.

As a reminder, all MAGEC patients should be followed clinically with the guidelines set out in the indications for use, including, but not limited to:

- The IFU should be consulted on an ongoing basis before and throughout patient treatment with the MAGEC System.
- 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.
- Device should be removed after implantation time of no more than six years.
- Device should be removed if skeletal maturity has been reached, or active distraction period had ended.
- Device should be removed and/or replaced if maximum distraction length of device has been achieved, and patient is still in active growth phase.
- During period of implant, patient should not participate in contact or severe sports such as weightlifting, tumbling, gymnastics, rowing, or other high risk activities.
- During period of implant, patient should limit backpack weight to 20% of body weight or less.
- During period of implant, patient should limit backpack weight to 20 lb (9 kg) or less.
- Patients should be limited to those having a BMI (body mass index) of 25 or less.

Affected Devices

All MAGEC System devices.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization.

This notice has been drafted in consultation with the appropriate regulatory authorities.

FIELD SAFETY NOTICE / MAGEC® SYSTEM

COMMERCIAL NAME: **MAGEC® System**
DATE: 1 April 2020
TYPE OF ACTION: Advisory Notice

Consignee Confirmation Form

It is important that your organisation takes the actions detailed in this FSN and confirms that you have received this FSN. Please complete and return this form to NuVasive per the instructions below.

Your organisation's reply is the evidence we need to monitor the dissemination of this notice.

Customer Name: _____
Address: _____
_____
_____
Phone: _____
(Information required for regulatory effectiveness check)

I acknowledge receiving and reading the 1 April 2020 MAGEC® SYSTEM FSN.

Name/Title	Signature	Date
NuVasive Representative, if applicable	Signature	Date

This form is to be returned to NuVasive

- Scan and email this form to FSNMAGEC@nuvasive.com