URGENT FIELD SAFETY NOTICE – MAGEC DEVICE SYSTEM

Date: December 1, 2021

Commercial Name: MAGEC Device System

Type of Action: Advisory Notice

NuVasive Specialized Orthopedics, Inc (NSO) voluntarily issues this Field Safety Notice (FSN) to inform healthcare providers of the following, in follow-up from the prior December 2020 FSN and April 2021 – NSO statement communications:

1. In December 2020, NSO informed healthcare providers of ongoing reviews of conformity to the essential requirements in Europe for the MAGEC Device System.
2. In April 2021, NSO alerted healthcare providers to
    a. The temporary suspension of the MAGEC Device System CE certificate by NSO's notified body DQS Medizinprodukte GmbH (DQS), and
    b. The institution of a global quality hold while additional evidence was reviewed by DQS and others.
3. As of November 19th, 2021, the CE certificate for the MAGEC Device System has been reinstated by DQS. This notice informs users of the removal of the CE suspension along with the following additional information:
    a. The MAGEC Device System instructions for use (IFU) document has been updated and is located at www.nuvasive.com/eIFU.

The following are the changes from the prior to the current MAGEC device system IFU. We recommend users with existing inventories maintain this FSN as a reference document:

From (current version):	***To (new version):**
Duration of implantation: Device should be removed after implantation time of no more than 6 years.	**Duration of implantation:** Device should be removed after implantation time of no more than 2 years.
Intended Use: The implanted rod is used to brace the spine during growth to minimize the progression of scoliosis. The rod includes a small internal magnet which allows the rod to be	**Intended Use:** The MAGEC system is indicated for skeletally immature patients less than 10 years of age with severe progressive spinal deformities (e.g., Cobb angle of 30 degrees or more;

lengthened by use of the External Remote Controller. The rod is implanted and secured using standard fixation devices (pedicle screws, hooks and/or connectors).	thoracic spine height of less than 22 cm) associated with or at risk of Thoracic Insufficiency Syndrome. TIS is defined as the inability of the thorax to support normal respiration or lung growth.
Cautions: This caution was not included.	**Cautions:** After two years implantation time, continued implantation may increase the rate of adverse events or complications.
Potential Adverse Event Section: These section was not previously included.	**Potential Adverse Events Section:** Added to the IFU: www.nuvasive.com/eIFU

Reasons for IFU Updates:

- Prior to this update, IFU language for the MAGEC Device System varied in different regions, specifically the duration of implantation and intended use statement sections.
- Aligning the instructions worldwide (excepting local IFU language requirements) will improve understanding of the use of the device by all healthcare providers.
- Clarifying the intended use statement helps ensure the device is used in those patients that have the potential for optimized benefits from the use of the device.

Clinical Impact:

There may be existing and prospective MAGEC patients who are impacted by this FSN. These patients include those who are currently implanted with MAGEC rod(s) beyond two years or who are implanted beyond the intended use population.

For those patients currently implanted beyond two years:

- A more conservative implantation duration of two years decreases the likelihood of certain *potential hazardous situations* and their associated harms. Examples of these harms are included in the *Potential Adverse Events* section of the IFU, available here: www.nuvasive.com/eIFU.
- However, removal and replacement of the MAGEC Device System during patient treatment introduces a *known harm* to the patient, reoperation and associated sequelae.
- Healthcare providers should review the updated IFU document and consult patients on these updates and assess care decisions in collaboration.

- Patients implanted with MAGEC should be assessed “at a minimum of once every six months,” per the IFU.

For those patients currently implanted outside of the updated intended use statement:

- Healthcare providers should review the updated IFU document and consult patients on these updates and assess care decisions in collaboration.
  - Patients implanted with MAGEC should be assessed “at a minimum of once every six months,” per the IFU.

Overview of the MAGEC System:

The MAGEC Device System is indicated for 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 is defined as the inability of the thorax to support normal respiration or lung growth.

Recommended User Action:

- An NSO representative will be contacting your office or you to help with any questions or concerns.
- Acknowledgement of these changes is critical. Please review, complete, sign and return the attached Consignee Confirmation Form in accordance with the directions on the form (accompanying this notification).
- If you have a patient with existing MAGEC implants please assess the updated IFU document and the “Clinical Impact” section above, as applicable.
- Forward this notice to anyone in your facility that needs to be informed.
- Direct any additional manufacturer inquiries to FSNmagec@nuvasive.com
- Report to NSO any adverse effect or product complaints related to the use of these devices to complaints@nuvasive.com, whether or not those adverse effects are related to this FSN.

The IFU should be considered when using the MAGEC Device System, including, but not limited to:

- The IFU should be consulted on an ongoing basis before and throughout patient treatment with MAGEC Device System.
- The device is not intended to be used in skeletally mature patients (e.g., patients with closed tri-radiate cartilage and/or a Risser score of 5).
- Device should be removed after the active distraction period had ended.
- Device should be removed after an implantation time of more than two years.

- After two years implantation time, continued implantation may increase the rate of adverse events or complications.
- Device should be removed if skeletal maturity has been reached (e.g., closed tri-radiate cartilage; skeletal maturity as defined by Risser Sign).
- Device should be removed or replaced if maximum distraction length of the device has been attained and the patient is not skeletally mature (e.g., closed tri-radiate cartilage; skeletal maturity as defined by Risser Sign).

Transmission of this Field Safety Notice:

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

This notice has been reported to all applicable regulatory authorities.

December 7, 2021

Matthew Collins
Vice President, Global Quality Assurance
101 Enterprise #100
Aliso Viejo, CA 92656

Date

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Consignee Confirmation Form

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

Your organization'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 December 1, 2021 MAGEC Device System FSN

Name/Title	**Signature**	**Date**
NSO representative, if applicable	**Signature**	**Date**

This form is to be returned to NSO – Scan and email this form to FSNmagec@nuvasive.com