December 7, 2021

Re: Update on MAGEC device system CE certificate and availability

Dear Surgeon Partners,

We are pleased to inform you the **CE certificate has been reinstated for the MAGEC device system.** The CE certificate reinstatement was supported by an extensive review by DQS Medizinprodukte GmbH (the Company's Notified Body) that included an assessment of clinical evidence, technical documentation, and biocompatibility testing results.

Product availability outside of the United States

At this time, **only MAGEC 1.5, along with limited MAGEC 2.0 inventory, is available for sale in countries that require a CE certificate. MAGEC X is available in countries that do not require a CE certificate and where the product is approved/registered.** Product availability will differ and be phased in by country as we work with local regulatory bodies on any country-specific requirements to reintroduce the MAGEC device system to a respective region. Please speak with your NuVasive representative on the status of product availability in your country.

Please note, the Company is actively engaged with our Notified Body to provide clarity on return of the redesigned MAGEC X (end cap) for CE countries (e.g., Europe). We will provide an update as soon as we have further information.

Updated Instructions for Use (IFU)

The Company updated the IFU for the MAGEC device system to align with the U.S. IFU. This provides a unified, global set of instructions to all users, subject to local IFU requirements. These updates include:

- Duration of implantation period: Device should be removed after implantation time of no more than two (2) years; and
- Clarity that the MAGEC device system is indicated for skeletally immature patients less than 10 years of age with severe progressive spinal deformities associated with or at risk of Thoracic Insufficiency Syndrome. See the full IFU for further details.

The updated electronic IFU can be found through the NuVasive website—click here. As a reminder, please consult the IFU prior to and during a patient's treatment with the MAGEC device system.

Field Safety Notice (FSN)

The Company has issued an FSN to notify you and other healthcare providers of the MAGEC device system's IFU updates. You will receive the FSN via email and a copy will be inserted in the product shipping box. **Please review and acknowledge the FSN and return it to NuVasive at your earliest convenience.**

This letter and the FSN is posted on our website for MAGEC notices. Please reach out to your NuVasive representative with any questions—our team is here to support you and your patients.

Sincerely,

Kyle T. Malone
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NuVasive, Inc.

Matthew Collins
Vice President, Global Quality Assurance
NuVasive, Inc.