July 15, 2021

Re: Availability of MAGEC X device in the U.S.

Dear U.S. Surgeon Partners,

We are pleased to inform you the **U.S. voluntary ship hold on the MAGEC device system has been lifted and the modified MAGEC X device is available for sale, effective immediately.** This decision was made after discussions between the U.S. Food and Drug Administration (FDA) and NuVasive Specialized Orthopedics, following a number of interactions over the last several months regarding available biocompatibility testing results, other available data, and the overall risks and benefits of the device.

In addition to this decision, the Company has utilized this time to streamline its MAGEC portfolio with a single product—the modified MAGEC X device (MAGEC 2b)—effective immediately. This device was cleared by the U.S. FDA in July 2020 (K201543) and is designed to mitigate endcap separation and related biocompatibility concerns. The Company will continue to support implanted MAGEC 1.5 and MAGEC 2 rods and existing field inventory, but it will no longer distribute MAGEC 1.5 and MAGEC 2 rods for sale.

Modified MAGEC X device (MAGEC 2b)

The Company has also updated the Instructions for Use (IFU) document to further clarify potential adverse events related to use of the device. See the electronic IFU section on the NuVasive website—click here—to reference the updated IFU. As a reminder, please consult the IFU prior to and during a patient's treatment with the MAGEC device, including reference to the indications for use population of skeletally immature patients less than 10 years of age and a duration of implantation time of two years.

This letter 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
Vice President, Clinical, Medical, & Regulatory Affairs
NuVasive, Inc.

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