Potential Concerns with NuVasive MAGEC System Implants - FDA Safety Communication

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The U.S. Food and Drug Administration (FDA) is informing patients, their caregivers, and health care providers of potential mechanical failures and concerns about tissue incompatibility (biocompatibility) associated with components of the following NuVasive Specialized Orthopedics' MAGEC devices:

- MAGEC Spinal Bracing and Distraction System
- MAGEC 2 Spinal Bracing and Distraction System
- MAGEC System
- MAGEC System Model X device
- MAGEC System Model X rod
- MAGEC System Rods

In February 2020, NuVasive issued an Urgent Field Safety Notice (https://www.nuvasive.com/wp-content/uploads/2020/02/Field-Safety-Notice-MAGEC-X.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) recalling its MAGEC devices to address a mechanical component failure where the endcap was separating from the rod part of the device. In July 2020, the FDA cleared a modified version of the MAGEC Model X rod, designed to mitigate endcap separation events.

Additional biocompatibility concerns potentially related to the existing endcap failures were raised in December 2020 when NuVasive issued an updated Field Safety Notice (https://www.nuvasive.com/wp-content/uploads/2021/04/MAGEC-FSN-December-2020.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) intended for customers in the European Union. In addition, the FDA began receiving reports in early 2021 describing local tissue reactions potentially related to endcap separation events with the MAGEC devices.

As NuVasive continues to investigate the root cause of these issues, the FDA is working with the manufacturer to evaluate new biocompatibility testing results and assess whether there is any clinically meaningful impact to patients with MAGEC devices.

Recommendations for Caregivers and Patients Considering a MAGEC Device

- Talk to a doctor about the benefits and risks of the MAGEC device. The FDA believes the benefits of a MAGEC device outweigh the risks for U.S. patients based on the current FDA-cleared indications for use and labeling. Indications for use and labeling may vary in other countries.

Recommendations for Patients Who Have a MAGEC Device and their Caregivers

- At this time, the FDA does not recommend the removal of functioning MAGEC rods prior to the two years after implantation.
- Be aware that if a patient experiences increasing levels of unexpected back pain with a MAGEC device, the health care provider should perform an additional examination of the patient's back, including obtaining x-rays to evaluate the condition of the MAGEC implant.
- If patients are experiencing a problem with a MAGEC device, the FDA encourages patients and their parents or caregivers to report the problem to their health care provider and to the FDA through the MedWatch Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

Recommendations for Health Care Providers

- Follow current U.S. labeling instructions (https://www.nuvasive.com/resources/electronic-ifu-information/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).
- Be aware MAGEC devices are:
    - Cleared for implantation for no more than two years.
    - To be implanted only in skeletally immature patients less than 10 years of age with severe progressive spinal deformities associated with or at risk of Thoracic Insufficiency Syndrome (TIS). See current device labeling (https://www.nuvasive.com/resources/electronic-ifu-information/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) for the complete Indications for Use Statement.
- Perform a full evaluation, including radiographs, of a patient, presenting with unexplained symptoms of back pain, inflammation, or deformity.
- Decisions about removing or exchanging a MAGEC device should be made by health care providers in consultation with the patient and their caregivers on a case-by-case basis. Discuss with patients and their caregivers that, at this time, the FDA does not recommend removal (prior to two years post implantation) of asymptomatic MAGEC devices that are stable and well-functioning.
- Report any adverse events or suspected events experienced with a MAGEC device through MedWatch, the FDA Safety Information and Adverse Event Reporting program

(/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).

Device Description

MAGEC is a growing spinal rod system intended for use in children under 10 years of age. MAGEC devices use magnets to help correct spinal deformities as the child grows. They are designed to help avoid multiple operations to correct the spinal curve.

Potential Risks Associated with MAGEC Devices

The FDA is aware of reports describing endcap separation, O-ring seal failure, and of potential exposure of internal components of this device to living tissue that may lead to adverse local tissue reactions.

Endcap Separation

In 2020, NuVasive made changes to the MAGEC device design to address endcap separation problems. The risk associated with endcap separation is unanticipated exposure of patient's tissue to internal components of the device that have not been completely tested for biocompatibility. In July 2020, the FDA cleared a new version of the MAGEC X rod, and this version of the MAGEC X device (MAGEC 2b) is designed to mitigate endcap separation. The recommendations in this communication apply to all MAGEC devices, including the modified MAGEC Model X rod cleared by the FDA in July 2020.

Biocompatibility

On April 5, 2021, and updated April 9, 2021, NuVasive informed health care providers of biocompatibility testing concerns, and voluntarily placed all MAGEC devices on a global ship hold (https://www.nuvasive.com/wp-content/uploads/2021/04/Company-statement_MAGEC-and-Precice-CE-Mark_09April2021.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

To evaluate whether the components covered by the endcap are biocompatible and to satisfy updated testing standards, NuVasive has been conducting additional biocompatibility testing. The FDA is working with the manufacturer to evaluate the new biocompatibility testing results.

On July 15, 2021, NuVasive posted an updated statement (https://www.nuvasive.com/wp-content/uploads/2021/07/Company_statement_MAGEC_X_availability_US_15July2021_Final.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) informing U.S. health care providers that the ship hold in the U.S. has been lifted for the MAGEC devices. The FDA believes it is in the best interest of patients to make the modified MAGEC X device available in the U.S. at this time because (1) the overall benefits of the device outweigh the known risks for on-label use in the U.S. compared to alternative treatments, (2) the U.S. indications and instructions

for use, which restrict use to patients less than 10 years old and for a two-year implantation time, further mitigate known risks, (3) the modified MAGEC X (MAGEC 2b) device, designed to mitigate endcap separation events and related biocompatibility concerns, will be the only device version currently available for sale in the U.S., and (4) the U.S. labeling has been updated to include a discussion of known risks associated with the device.

FDA Actions

The FDA is working with NuVasive to:

- Evaluate additional biocompatibility testing intended to address specific theoretical biocompatibility concerns with these devices and collect additional data to better understand potential risks to patients.
- Provide health care providers and patients access to an adequate supply of modified MAGEC devices, which are magnetically distractable growing rods designed to reduce the number of surgeries needed compared to alternatives.
- Ensure patients with a MAGEC implant continue to receive appropriate follow-up monitoring.

The FDA will keep the public informed if significant new information becomes available.

Reporting Problems with a MAGEC Device

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with NuVasive MAGEC device system implants.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).
- Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV) or call 800-638-2041 or 301-796-7100.