



URGENT FIELD SAFETY NOTICE / MAGEC® SYSTEM

DATE: June 25, 2019

COMMERCIAL NAME: **MAGEC® System**

TYPE OF ACTION: Advisory Notice

MAGEC® System manufactured prior to March 26, 2015

Description of the Issue:

Post-implantation fracture of an internal metallic component (i.e., locking pin) has been observed in early versions of MAGEC® System Rods (devices) that were manufactured prior to March 26, 2015. Post-market surveillance data have shown this issue to have occurred in approximately 5% of the total number of devices manufactured prior to March 26, 2015. These devices are no longer available for sale or implantation. Post-market surveillance data indicate that MAGEC® System devices manufactured on or after March 26, 2015, do not exhibit the same issue.

Clinical Impact:

The MAGEC® System is used to brace the spine during growth to minimize the progression of scoliosis. Metallic implants can loosen, fracture, corrode, migrate, or cause pain. Fracture of the locking pin may affect the ability of the device to lengthen and may be associated with Titanium wear debris generation and localized tissue discoloration. Post-market surveillance data have not revealed clinical symptoms related to localized tissue discoloration or Titanium wear debris. In addition, a locking pin fracture does not necessarily indicate a failure of the device to serve its function as an internal brace.

Recommended User Action:

NuVasive, Inc. voluntarily issues this Field Safety Notice (FSN) to reinforce the Instructions for Use (IFU) of the MAGEC® System to clinical users

- The IFU should be consulted on an ongoing basis 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. Typically, the device can be adequately visualized, and a fractured locking pin can be detected, on standard anteroposterior X-ray imaging. Figure 1 shows representative X-ray images for comparison of a device with an intact locking pin (A) to a device manufactured prior to March 26, 2015 with a fractured locking pin (B). A fractured locking pin can typically be identified by examining the noted areas to detect the separation of the internal components and/or the extension of an internal component beyond the device housing.

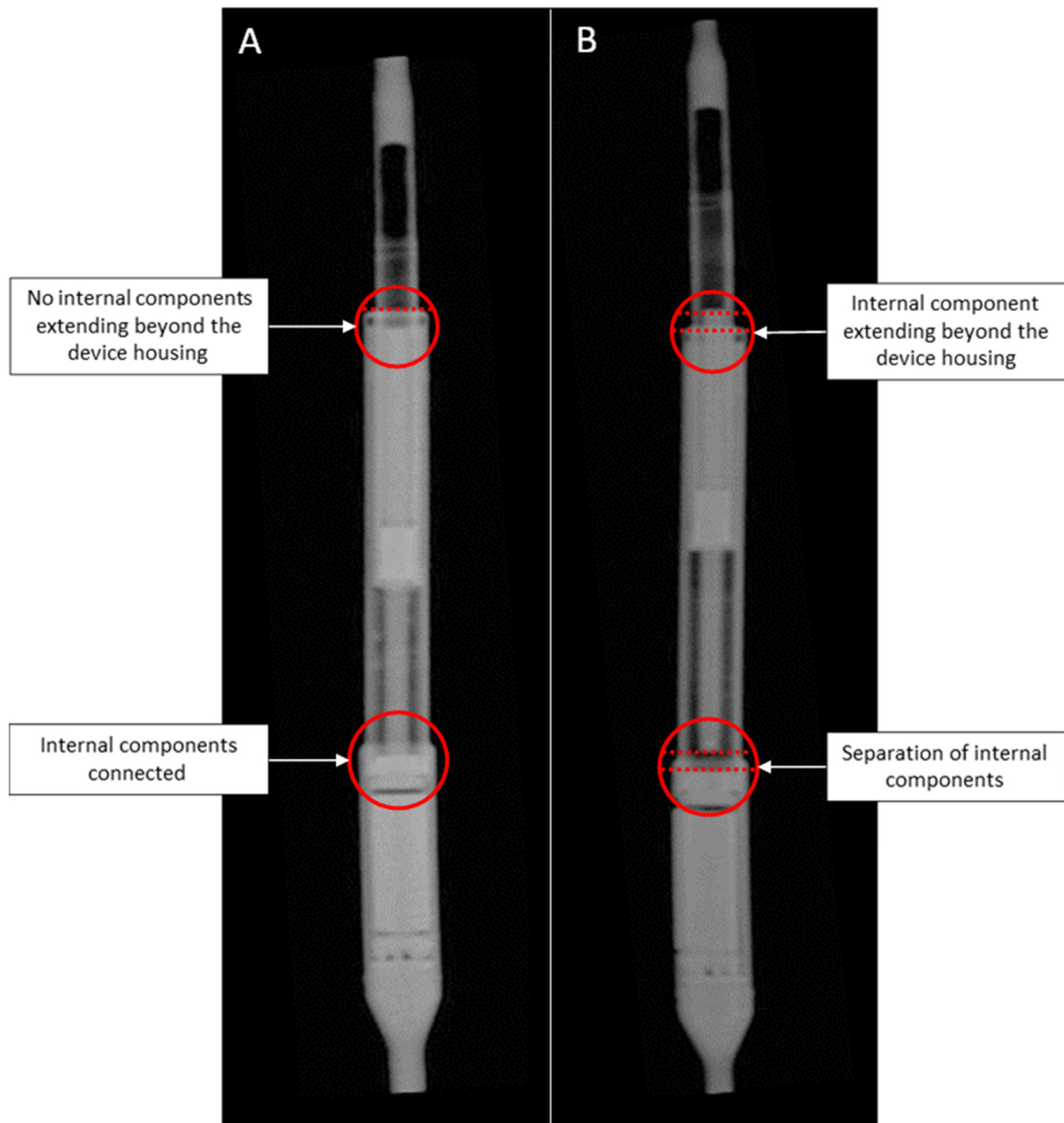


Figure 1: Representative X-ray images of a device with an intact locking pin (A) and a device manufactured prior to March 26, 2015 with a fractured locking pin (B). Visual Identifiers of a fractured locking pin can include separation of internal components and the extension of an internal component beyond the device housing.

- If a fractured locking pin is detected, removal of the device may be indicated. The decision to remove the device should be made by the physician in consultation with the patient and/or family.
- If removal is deemed appropriate by the physician, the device and all associated accessories should be removed and the explanted device should be returned to NuVasive.
- Clinical users should review the IFU and be aware of the warnings and precautions on an ongoing basis throughout patient treatment with the device.
- Patients and/or families should be reminded of the importance of following the postoperative care instructions in the IFU.

Warnings and Precautions relevant to the Issue:

The following warnings and precautions of the IFU are reinforced by this FSN. They are of particular relevance to clinical users to assist when making clinical decisions with patients and in addressing the Issue:

- Metallic implants can loosen, fracture, corrode, migrate, or cause pain.
- Use of the MAGEC® Rods may result in localized tissue discoloration.
- 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 has 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.
- Ensure that the distraction length is assessed by X-ray imaging immediately after non-invasive adjustment procedure, and also at a minimum of once every six months.

Affected Devices and Support:

To determine whether a device was manufactured prior to March 26, 2015, follow the instructions below.

- To determine the date of manufacture, identify the 6-digit numerical string within the lot number. The device lot number is provided on the label and/or recorded in the patient record. A representative patient chart label is shown in Figure 2.



Figure 2: Representative patient chart label showing device lot number. The 6-digit numerical string (e.g. 130508) is indicated by the red box.

- If the 6-digit string (indicated by the red box in Figure 2) is numerically less than the 150326, then the device was manufactured prior to March 26, 2015.
- If the 6-digit numerical string is greater than or equal to 150326, or the lot number format is different than the format shown in Figure 2, then the device was manufactured after March 26, 2015.

Alternatively, users can submit the device lot number on the following webpage - www.nuvasive.com/fsnmagec - to determine whether that device was manufactured prior to March 26, 2015.

If you need any further information or support concerning this issue, please email FSNMAGEC@nuvasive.com.



Incidents of device failure should be promptly reported to the Company, irrespective of whether the failure is related to this FSN.

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 submitted to the appropriate regulatory authorities.

A handwritten signature in black ink that reads 'C. Bleakley'.

Carol Bleakley, PhD

Vice President, Regulatory Affairs and Quality Assurance
NuVasive, Inc. • Transforming Spine Surgery and Beyond.



URGENT FIELD SAFETY NOTICE / MAGEC® SYSTEM

COMMERCIAL NAME: **MAGEC® System**

DATE: June 25, 2019

TYPE OF ACTION: Advisory Notice

Effectiveness Check 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 progress of the corrective actions.

Customer Name: _____
Address: _____

Phone: _____
(Information required for regulatory effectiveness check)

I acknowledge receiving and reading the June 25, 2019 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