



URGENT FIELD SAFETY NOTICE / MAGEC® SYSTEM

DATE: February 13, 2020

COMMERCIAL NAME: **MAGEC® System**

TYPE OF ACTION: Advisory Notice and Product Recall

MAGEC® System

NuVasive, Inc. voluntarily issues this Urgent Field Safety Notice (FSN) to inform healthcare providers caring for patients with MAGEC® System Model X rods of the following information.

Description of the Issue:

Post-implantation separation of an actuator end cap component has been observed in MAGEC® System Model X rods. Post-market surveillance data have shown this actuator end cap separation to have occurred in approximately 0.5% of this device.

This issue has only been observed in Model X rods, and therefore the prior version rods of the MAGEC® System are not affected by this FSN. Model X rods were first manufactured on July 27, 2017; the list of all potentially affected Model X lots are attached to this FSN.

The root cause of this issue is currently under investigation.

Clinical Impact:

Separation of the end cap may expose internal components of the actuator, which could lead to hastened degeneration of the internal components and egress of Titanium alloy wear debris and resultant localized tissue discoloration.

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. A Model X MAGEC® System rod may continue to lengthen/distract and/or serve as an internal brace after the separation of the end cap component. The long-term ability of a rod with a separated actuator end cap to continue to lengthen/distract is currently unknown.

The company recommends that surgeons perform routine clinical follow-up and discuss potential clinical implications and risks with patients who received affected rods. NuVasive is not recommending prophylactic revision based solely on the separation of an end cap. However, if an end cap separation 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.

Recommended User Action:

- Immediately examine your inventory to determine if you have product subject to this action on hand and quarantine the product. Your NuVasive representative will be visiting your office or contacting you directly to provide instructions for the return of the Model X rods.
- Review, complete, sign and return the attached Consignee Confirmation Form accompanying this notification in accordance with the directions on the form.
- Do not implant Model X rods until further notice.
- Review the details below and understand how to identify a separated end cap on postoperative X-Ray imaging as shown in Figure 1 below.

- Users should follow the appropriate postoperative procedure to assess the Model X rod 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 separated end cap can be detected, on standard anteroposterior X-ray imaging.
- If an end cap is seen to have separated from the actuator, the decision to remove the device should be made by the physician in consultation with the patient and/or family.
- If a Model X rod with a separated end cap is removed, confirm that the end cap is retained on the rod and that the actuator housing and distraction rod remain intact at all times during explantation.
- If removal is deemed appropriate by the physician, the device and all associated accessories should be removed and the explanted device returned to NuVasive.
- Patients and/or families should be reminded of the importance of following the postoperative care instructions in the IFU.
- Forward this notice to anyone in your facility that needs to be informed.

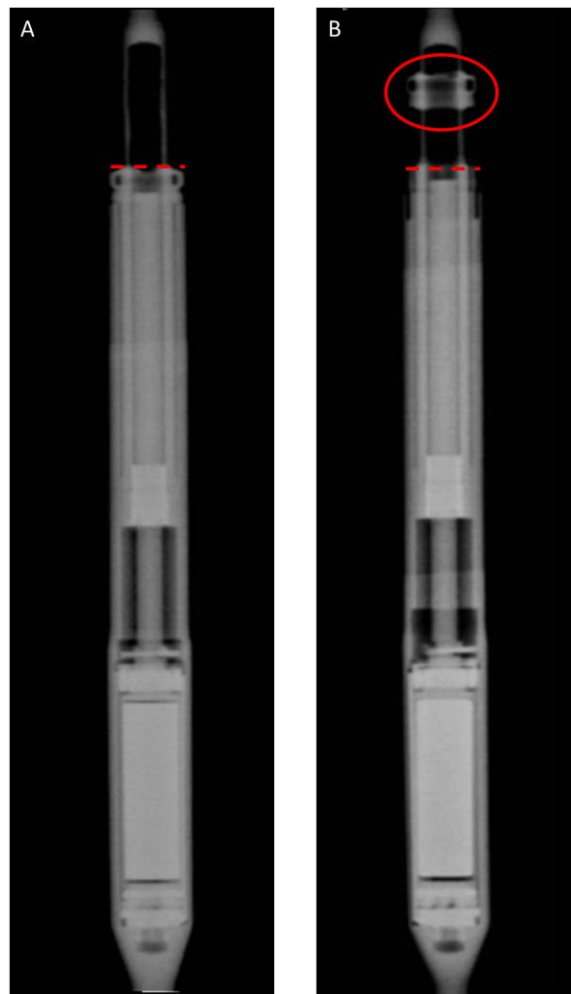


Figure 1: Representative X-ray images of a device with a seated end cap (A) and a device with a separated end cap (B). Visual Identifiers of a separated end cap can include separation of the end cap from the device actuator housing.

Affected Devices

The list of all affected lots is attached to this FSN.



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

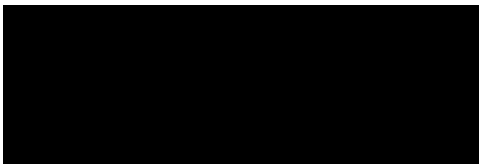
Transmission of this Field Safety Notice:

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.

We apologize for any inconvenience that this action may create and appreciate your cooperation with our request.

If you have any questions or would like assistance with this FSN, please contact NuVasive at FSNMAGEC@nuvasive.com.



NuVasive, Inc. • Transforming Spine Surgery and Beyond.



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Consignee Confirmation 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 February 13, 2020 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

MAGEC X Lot Numbers

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