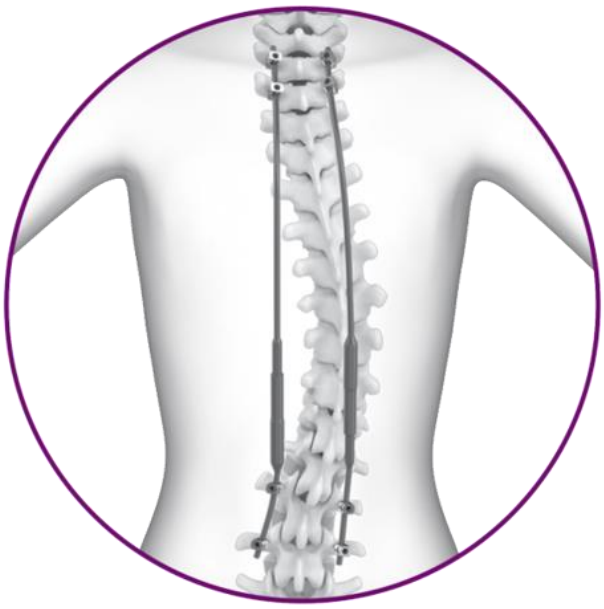
Safety Communication

MAGEC System - Post-implantation fracture of an internal metallic component

Device/ Product Description:	MAGEC System
Brand Name:	Nuvasive
Lot numbers/Serials:	Devices manufactured prior to March 26, 2015
Manufacturer:	Nuvasive Specialized Orthopaedics Inc.
Problem:	Nuvasive advises that 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. 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 shown this issue to have occurred in approximately 5% of the total number of devices manufactured prior to March 26, 2015.
Recommendation/ Actions:	• 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. • Patients and/or families should be reminded of the importance of following the postoperative care instructions in the IFU. • You can find more information and recommendations from (Here).

Devices/Products photo:		
Authorized Representative Details	**Company name:**	**Nuvasive Specialized Orthopaedics Inc.**
	Contact Person:	**Shadi F. Qudsi**
	Phone:	**+012 6601149**
	Email:	**Squdsi@amicogroup.com**

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative of your product for corrective action.
Healthcare Professionals should **report any adverse events** suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority
4904 northern ring branch rd - Hitteen Dist.
RIYADH 13513 - 7148
Tel: +966 (11) 2038222 Ext: 2995, 2952
Fax: +966 (11) 2757245
Or
Saudi Vigilance
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Sincerely,
NCMDR Team