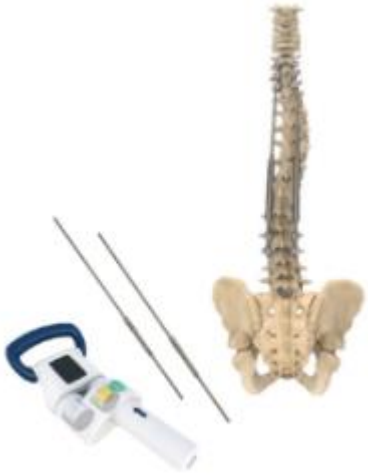
Safety Communication رسالة سلامة

Recommendations for Healthcare Providers Regarding Some Concerns with NuVasive MAGEC System Implants

Device/ Product Description:	Growing Spinal Rod System - MAGEC
Manufacturer:	NuVasive Specialized Orthopedics Inc.
Problem:	A potential risk of fracture at the locking pin located inside the internal metallic components of the device.
Recommendation /Actions:	1. Consult the instruction for use (IFU) on an ongoing basis prior and posterior of patient therapy with the MAGEC system. 2. Explant the MAGEC device as soon as possible if any component of the device is not intact, only when the removal will not cause additional harm to the patient. 3. Remove the device as soon as possible if the rod is not distracting anymore, only when the removal will not cause additional harm to the patient. 4. Takeout the implanted MAGEC system at the end of the distraction treatment, only when the removal will not cause additional harm to the patient. 5. Apply the following to ensure that the MAGEC system is functioning properly: • Continuous postoperative follow-up according to the normal procedures and as clarified in the IFU. • Remind the patients of the importance of following the postoperative care procedures to evaluate the state of the MAGEC System by X-ray imaging, whenever the device is adjusted or at a minimum of once every six months. • The most recent x-ray image should be assessed and compared to the immediate post-operative image to help identify signs of device failure, including component fracture or migration.

	6. Be cognizant and up to date of all published safety communications regarding the MAGEC system. 7. Inform patients and their families of the relative risk combined with the MAGEC system implantation. 8. Make sure to report any adverse event that relate to the implant through the National Center for Medical Devices Reporting (NCMDR) system: https://ncmdr.sfda.gov.sa, or Saudi Vigilance System https://ade.sfda.gov.sa/ Or by calling 19999.	
Image:		
Authorized Representative Details	AR name:	Al Amin Medical Instruments Co Ltd
	Assigned Contact Person:	Bayan Sultan
	Mobile/Phone:	+(966) 557141410
	Email:	sfdaksa@amicogroup.com