

Safety Communication

رسالة سلامة

Updated (IFU) for MAGEC Device System

Device/ Product Description:	MAGEC Device System	
Lot/Serial Number:	ALL	
Manufacturer:	NuVasive Specialized Orthopedics, Inc	
Problem:	The MAGEC Device System instructions for use (IFU) document has been updated	
Recommendation/Actions:	The following are the changes from the prior to the current MAGEC device system IFU.	
	From (current version):	*To (new version):
	Duration of implantation: Device should be removed after implantation time of <u>no more than 6 years.</u>	Duration of implantation: Device should be removed after implantation time of <u>no more than 2 years.</u>

	<p>Intended Use:</p> <p>The implanted rod is used to brace the spine during growth to minimize the progression of scoliosis. The rod includes a small internal magnet which allows the rod to be lengthened by use of the External Remote Controller. The rod is implanted and secured using standard fixation devices (pedicle screws, hooks and/or connectors).</p>	<p>Intended Use:</p> <p>The MAGEC system is indicated for skeletally immature patients less than 10 years of age with severe progressive spinal deformities (e.g., Cobb angle of 30 degrees or more; thoracic spine height of less than 22 cm) associated with or at risk of Thoracic Insufficiency Syndrome. TIS is defined as the inability of the thorax to support normal respiration or lung growth.</p>
	<p>Cautions:</p> <p>This caution was not included.</p>	<p>Cautions:</p> <p>After two years implantation time, continued implantation may increase the rate of adverse events or complications.</p>
	<p>For more information, Please click here and here.</p> <p>If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system (19999) unified call center</p>	
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