Safety Communication رسالة سلامة

Complications Related to Cardiac Perforation During Implantation

Device/ Product Description:	Micra leadless pacemaker
Affected product:	All
Manufacturer:	Medtronic SA
Problem:	Risk of major complications if cardiac perforation occurs during leadless pacemaker implantation.
Recommendation /Actions:	• Discuss the risks and benefits of available pacemaker system options with patients as part of shared clinical decision-making. • Read and carefully follow the Instructions for Use (IFU) and training for the Medtronic leadless Micra Transcatheter Pacing System, which include recommendations about implant location at the right ventricle septum, delivery system steering, repositioning the device, patient selection to minimize perforation risk, stand-by availability of cardiothoracic surgery, and immediate access to echocardiography equipment. • Report any adverse events or suspected adverse events experienced with the Micra Transcatheter Pacing System or other pacemaker systems.

	For more information, please click here. 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	
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