

Safety Communication

رسالة سلامة

Potential for a wire protrusion through the left heart vent catheter tip

Device/ Product Description:	Left Heart Vent Catheters	
Manufacturer:	Medtronic	
Affected devices:	Product Name	Model Numbers
	DLP® Left Heart Vent Catheters, 16 Fr	12116
	DLP® Left Heart Vent Catheters, 18 Fr	12118
Problem:	Potential for a wire protrusion through the left heart vent catheter tip. If unnoticed prior to the procedure, this wire protrusion could lead to tissue damage (abrasion/perforation) and thereby to a longer duration of the procedure and/or surgical repair.	
Recommendation /Actions:	<ul style="list-style-type: none"> • Make sure that this document is reached to the end-users. • Identify and quarantine all unused affected devices. • Contact the authorized representative for the required support. <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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