Medtronic

The purpose of this communication is to provide a response on Regulatory Inquiries that Medtronic has received regarding the Urgent Field Safety Notice Medtronic sent on 13July2026 for the following device:

Product Name	GTIN, UDI	Model	Lot Number(s)	
Sphere-360™ Pulsed Field Ablation Catheter	*199150027590*	*AFR-00012*	*Q060500231* *Q060500592* *Q060400906* *Q060400388*	*Q060400519* *Q060400510* *Q060400215* *Q060300271*

Updated Issue Description:
During the Sphere-360™ Pulsed Field Ablation Catheter commercial launch in the EU beginning 22June2026, nine (9) complaints were received reporting discoloration on the catheter tip. Given the observed occurrence rate and the unknown nature of the discoloration, Medtronic initiated a Product Hold Order (11July2026), Field Action (13July2026), and Issue PR (13July2026). The field action was focused on the discoloration concern.

A formal Health Risk Assessment (HRA) was subsequently completed and expanded to include reports of guidewire extension/retraction difficulty, as well as two (2) additional complaints received after the field action, for a total of eleven (11) complaints. Of the eleven complaints, seven (7) included guidewire extension/retraction difficulty, including one (1) report that also noted insufficient treatment. No clinical adverse events were reported.

The Customer Actions Medtronic Communicated Remain Unchanged:

- Immediately segregate Sphere-360™ catheter lots in their facility to prevent use.
- Pause any planned cases with Sphere-360™ catheters.
- Please complete and return the Customer Acknowledgement Form, acknowledging they received the information, and pass on this notice to all those who need to be aware of this information within their organization or to any organization where the listed affected lots may have been transferred or distributed.

The investigation remains ongoing. At this time, affected product remains segregated to prevent use, and Medtronic has paused additional shipments of Sphere-360™ product. Medtronic continues to evaluate investigation findings, returned product evaluations, and risk information to determine whether additional field actions, product retrieval, or customer communications are warranted. An update to customers is expected in approximately the next 30 business days.

Additional Updates:
The Health Risk Assessment (HRA) recommended mitigation of risk in the field. Medtronic had already implemented risk mitigation actions, including customer notification, product segregation, paused use of affected lots, and suspension of additional product shipments.

While no clinical adverse events have been reported, the HRA has identified the following observed and/or potential risks that could be associated with the observed failure modes.

Harm Severities	Observed and/or Potential?	Applicable harm(s)
Critical	Potential	Embolism
Major	Observed	Insufficient Treatment
	Potential	Cardiac/vascular tissue injury, serious; collateral tissue injury, serious
Minor	Observed	Delay of case – replace device
	Potential	Embolism, minor (asymptomatic, without sequelae); collateral tissue injury, minor
Negligible	Observed	No injury to patient

Note: No patient subpopulations at higher or increased risk have been identified at this time.

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As of 27July2026, Medtronic has received and begun evaluating returned devices through established QMS processes. The investigation remains ongoing, and it has not yet been determined whether the reported observations are attributable to a product issue or other contributing factors. A CAPA has been initiated, and investigation planning, root cause analysis, and timeline development are underway to determine any appropriate corrective actions. The investigation is expected to take 8 weeks to complete.

We regret any inconvenience this may cause. While planned cases utilizing Sphere-360™ catheters should remain paused, there is no anticipated interruption to patient care because alternative Medtronic ablation catheters are available, as clinically appropriate and in accordance with approved labeling for paroxysmal atrial fibrillation ablation procedures, including Sphere-9™, PulseSelect™, and Arctic Front Advance™. We remain committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,