

Urgent Field Safety Notice

Sphere-360™ Pulse Field Ablation Catheter

Notification

GTIN, UDI	Model	Lot
199150027590	AFR-00012	Q060500231
		Q060500592
		Q060400906
		Q060400388
		Q060400519
		Q060400510
		Q060400215
		Q060300271

July 2026

Medtronic Reference: FA1586

EU Manufacturer Single Registration Number (SRN): US-MF-000019977

Dear Healthcare Professional/Risk Manager:

The purpose of this communication is to advise you that Medtronic has initiated an Urgent Field Safety Notice for specific Sphere-360™ catheter lots.

Issue Description:

Between July 02 and July 10, 2026, Medtronic has received nine (9) complaints potentially associated with a device anomaly observed in the form of discoloration of the distal device tip. No clinical adverse events or patient safety harms have been reported in association with these complaints.

Medtronic is currently investigating the issue. However, out of an abundance of caution (while the investigations are continuing), Medtronic is requesting an immediate pause on the commercial use of the above-mentioned Sphere-360™ catheter lots.

Customer Actions:

- Immediately segregate Sphere-360™ catheter lots in your facility to prevent use.
- Pause any planned cases with Sphere-360™ catheters.
- Pass on this notice to all those who need to be aware within your organization or to any organization where the listed affected lots may have been transferred or distributed.



As we further investigate the issue, we will follow up with more detailed communication and any additional actions that may be required.

Additional Information:

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Representative.

Sincerely,

A handwritten signature in blue ink, appearing to read "Sebnem Yavas Hoffsten".

Sebnem Yavas Hoffsten

Quality & Regulatory Affairs Manager