Medtronic

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.
- Please complete and return the Customer Acknowledgement Form enclosed with this letter, acknowledging that you have received this information.
- 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.

Medtronic

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,

Maria Artamonova

Associate Regulatory Affairs Specialist – UK and Ireland

Enclosures:

Attachment A: Customer Acknowledgement Form

Medtronic

FA1586 Customer Acknowledgement Form - Response is required
Sphere-360™ Pulse Field Ablation Catheter

Please complete this Form in its entirety.

Date: _____

Name of Person Completing this Form: _____

Title:_____

Direct Phone #:_____

Email:_____

Account Name:_____

Account Number:_____

Account Address:_____

City: _____Zip Code:_____

Country:_____

_____

I have read and understand the instructions provided and acknowledge receipt of the **notification** regarding the use of the **Sphere-360™ Pulse Field Ablation Catheter** by signing below. I also agree to further distribute and communicate this important information within my facility and to anyone whom I have further distributed **Sphere-360™ Pulse Field Ablation Catheter** as required.

_____ _____ _____

Name: (print) Signature: Date:

If you have any questions regarding this notification, please contact your Medtronic sales representative.

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO: rs.fsnuki@Medtronic.com .