Medtronic

URGENT FIELD SAFETY NOTICE

Esoflip™ dilation catheter 30mm – Model # ES-330

Recall

April 2024

Medtronic Reference: FA1413

EU Manufacturer Single Registration Number (SRN): US-MF-000028763

Dear Healthcare Provider/Risk Manager,

The purpose of this letter is to advise that Medtronic is initiating a recall of the Esoflip™ dilation catheter 30mm – Model # ES-330, for the specific lot numbers listed below.

Issue Description:

Medtronic has determined that devices within specific lot numbers of Esoflip™ dilation catheter 30mm – Model # ES-330 may have non-conformances in saline conductivity that could negatively impact the performance of the product as indicated. If such devices are used, inaccurate esophageal diameter measurements may lead to these harms: delay to treatment, pain, bleeding, esophageal laceration, esophageal perforation, or respiratory distress.

From 01 April 2022 through 31 March 2024, there were 167 complaints related to catheters with low saline conductivity.

Product Scope:

Brand Name	Model Number	GTIN Number	Affected Lot Number
Esoflip™ dilation catheter 30mm	ES-330	20884521809458	22K0854JZ, 23A1202JZ

Customer Actions:

- Immediately identify and quarantine all unused Esoflip™ dilation catheter 30mm – Model # ES-330 from the affected lot numbers.
- Return all unused affected product(s) in your inventory to Medtronic.
- Please complete and return the enclosed Customer Acknowledgement Form, even if you have no product to return.

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- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which this action has an impact.
- Please maintain a copy of this notice in your records.

Patient Recommendations:

There are no additional actions required for patients where an Esoflip™ dilation catheter 30mm – Model # ES-330 was used during a procedure. These patients should continue to be monitored in accordance with your medical facility's standard care protocols.

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 local Medtronic representative.

Sincerely,

Local / OU Manager

Enclosure:
Customer Acknowledgement Form