

URGENT FIELD SAFETY NOTICE

Octopus™ Tissue Stabilizer - Canister Incorrect Tubing Configuration

Recall

Product Description	Model Number	GTIN-UDI
Octopus™ Nuvo Tissue Stabilizer	TSMICS1	00763000543693

May 2026

Medtronic Reference: FA1541

Dear Healthcare Professional/ Risk Manager,

The purpose of this letter is to advise you that Medtronic is initiating an Urgent Field Safety Notice involving specific lots of one (1) model within the Octopus™ Tissue Stabilizer product line. Our records indicate that you have received product that is within the scope of this Urgent Field Safety Notice. Please note that no additional lot numbers are impacted by this communication.

Issue Description:

During the manufacturing process, Medtronic personnel identified an assembly issue where the canister vacuum tubing was incorrectly connected. The short tube was attached to the bottom of the canister, and the long tube was attached to the top, contrary to the intended design. After further investigation, this issue impacts specific lots of one (1) model of the Octopus™ Tissue Stabilizer product line.

Up until March 27, 2026, Medtronic has not received any reports related to this issue. If an attempt is made to use the product, the device will not function as intended.

Medtronic

Customer Actions:

Medtronic requests that you take the following actions:

- Review your inventory for lot numbers listed in Attachment A.
- If you have unused inventory from the listed lot numbers, immediately quarantine and return the products to Medtronic, and referencing this communication to initiate return and exchange or credit of this unit. Your Medtronic sales representative can assist you in the return of unit as necessary.
- Please complete and return the enclosed Customer Acknowledgment Form **even if you do not** have any affected products in your inventory, to acknowledge that you have read and understand this letter.
- Please share this notification with others in your organization as appropriate. If product listed above has been forwarded to another facility, please notify the facility of this Urgent Field Safety Notice.
- Please maintain a copy of this communication in your records.

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,

Local / OU manager

Enclosed:

- Attachment A: List of impacted lots

Attachment A - List of impacted lots

Product Name	Model/Catalog Number	Lot Number
Octopus™ Nuvo Tissue Stabilizer	TSMICS1	0232805458