

URGENT FIELD SAFETY NOTICE

Progrip™ Self-Gripping Polyester Mesh

Wrong Product in Packaging

Recall

November 2024

Medtronic Reference: FA1456
EU Manufacturer Single Registration Number (SRN): FR-MF-000012211

Dear Risk Manager/Healthcare Professional/Distributor

The purpose of this letter is to notify you of recall for 2 lots of Progrip™ Self-Gripping Polyester Mesh (TEM1515G, lot number SYF0272X and TEM1509G, lot number SYF0106X). You are receiving this letter as Medtronic records indicate your facility may have the potentially affected lot of the Progrip™ Self-Gripping Polyester Mesh.

Issue Description:

This recall is being conducted due to incorrect device size being contained in the package. Medtronic received complaints for the Progrip™ Self-Gripping Polyester Mesh reported as wrong product size in package from lot number SYF0272X and SYF0106X.

For lot number SYF0272X, products were packaged and labelled as Progrip™ Self-Gripping Polyester Mesh Reorder Code 15x15 (cm): TEM1515G (batch #SYF0272X), however some packages contained Progrip™ Self-Gripping Polyester Mesh Reorder Code 9x15 (cm): TEM1509G mesh inside.

For lot number SYF0106X, products were packaged and labelled as Progrip™ Self-Gripping Polyester Mesh Reorder Code 09x15 (cm): TEM1509G (batch #SYF0106X), however some packages contained Progrip™ Self-Gripping Polyester Mesh Reorder Code 15x15 (cm): TEM1515G mesh inside.

No serious patient injuries or patient harms related to this issue have been reported.

Product Scope:

Product Name	Model Number	GTIN	Lot Number	Manufacturing date (DD/MM/YYYY)	Expiration Date (DD/MM/YYYY)	Qty
Progrip™ Self-Gripping Polyester Mesh	TEM1515G	10884521177727	SYF0272X	06/06/2024	31/05/2029	7
	TEM1509G	10884521177673	SYF0106X	05/06/2024	31/05/2029	0

Medtronic

Customer Actions:

- Immediately identify and quarantine unused affected ProGrip™ Self-Gripping Polyester Mesh with associated lot number listed above.
- Return all unused affected ProGrip™ Self-Gripping Polyester Mesh from your inventory to Medtronic as described on the Customer Acknowledgement Form.
 - Credit will be issued for the returned unused affected product.
 - If purchased from a distributor, contact your distributor directly to arrange for the return of the product back to your distributor.
 - Contact your local Medtronic Surgical Representative for support to return unused affected ProGrip™ Self-Gripping Polyester Mesh in your possession.
- Please complete the Customer Acknowledgment Form even if you **do not** have unused inventory.
- This notice should be passed on to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred. Please maintain a copy of this notice 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 Sale Representative.

Sincerely,

[Local / BU Manager](#)

[Enclosure:](#)

[Customer Acknowledgement Form](#)