Medtronic

Medical Surgical
Surgical
60 Middletown Avenue
North Haven, CT 06473
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URGENT: MEDICAL DEVICE RECALL

Progrip™ Self-Gripping Polyester Mesh

Wrong Product in Packaging

November 2024

Dear Risk Manager/Healthcare Professional/Distributor:

The purpose of this letter is to notify you of a medical device 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 voluntary 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	475
	TEM1509G	10884521177673	SYF0106X	05/06/2024	31/05/2029	473

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. Please contact: rs.covidienfeedbackcustomerservice@medtronic.com for the Return Good Authorization (RGA).
    - Credit for the returned affected product will be issued based on the RGA number

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- 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 Spine Representative to return unused affected Progrip™ Self-Gripping Polyester Mesh in your possession.

- Complete and return the Customer Confirmation Form enclosed with this letter to rs.gmbmitgfca@medtronic.com, acknowledging that you have received this information.
- 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.

Return Instructions:

Product purchased directly from Medtronic please contact: connect.medtronic.com or rs.covidienfeedbackcustomerservice@medtronic.com.

Additional Information:

Medtronic will communicate this information to the appropriate regulatory agency in your country.

Local contact details:

Adverse reactions or quality problems experienced with this product should be reported to FDA and Medtronic:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or
- Call FDA (800) FDA-1088

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,

Kristy Simmons
VP Quality, Surgical
Medtronic, Inc.

Enclosure:
Customer Confirmation Form