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Urgent Field Safety Notice

Parietex™ Opposite Mesh Position

Recall

Product Name	Model Number	Lot Number	Product GTIN
Parietex™ Composite Mesh Polyester with Absorbable Collagen Film, Horseshoe-Shaped, 9 x 8 cm (3.6" x 3.1")	PCO2H3	PVE0194M	A8845211784602

January 2023

Medtronic Reference: FA1303

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

Dear Risk Manager/Healthcare Professional/Distributor:

The purpose of this letter is to advise you that Medtronic is voluntarily initiating a recall for one lot of the Parietex™ Composite Mesh (PCO2H3, lot #PVE0194M), designed for hiatal hernia repair. You are receiving this letter as Medtronic records indicate your facility may have the potentially affected lot of the Parietex™ Composite Mesh.

Issue Description:

Through 16 December 2022, Medtronic has received two (2) complaints in relation to Parietex™ Composite Mesh; both complaints were identified prior to patient contact. The two (2) complaints in relation to Parietex™ Composite Mesh (PCO2H3, lot #PVE0194M) manufactured at the Trevoux, France facility, reported that the collagen film was placed on the opposite side of the mesh. A visual examination of the returned product confirmed the root cause as a manufacturing issue. In both cases, another mesh was used to resolve the issue to complete the case, and there was no patient contact with the product. No serious patient injuries or patient harms related to this issue have been reported.

The potential harms may include a delay to treatment/therapy, adhesions, erosion/migration, pain, fistula, hernia (recurrence), and failure of implant (delay/compromised mesh-tissue integration). If Parietex™ Composite Mesh with collagen film on the wrong side is encountered in the operating room setting, please discard the product and use additional, correct mesh product instead.

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There are no additional patient management recommendations for patients where potentially affected meshes in scope of this recall were used during a procedure. These patients should continue to be monitored in accordance with your medical facility's standard care protocols with consideration to the specific use, and clinical staff should properly assess and manage patients for any adverse clinical outcomes, including those associated with this recall condition.

Actions:

- Identify (see attachment A) and quarantine all unused and non-expired product from the affected lot (PVE0194M) of Parietex™ Composite Mesh.
- If Parietex™ Composite Mesh with collagen film on the wrong side is encountered in the operating room setting, please discard the product and use additional, correct mesh product instead.
- In the event it is determined by a medical facility that an affected product was implanted during a procedure, that facility should follow its medical record management procedures to ensure that this recall condition is properly noted for that procedure and documented to ensure traceability.
- Please complete the Customer Acknowledgment Form even if you **do not** have unused inventory.
- Return all unused and non-expired product from the affected lot in your inventory to Medtronic as indicated in the Shipping and Return Instructions below.
- Pass on this notice to all those who need to be aware within your organization or to any organization where the potentially affected product within the specified lot has been transferred or distributed.

Shipping and Return Instructions:

	Customer with inventory	**Customer with zero inventory**	**Where to send the completed form**
Purchased **directly** from Medtronic	Please complete the attached Returns Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to the Medtronic contact provided on the verification form.
Purchased from a **distributor**	Complete **all** fields on the form and contact your distributor directly to arrange for return of product.	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to your Distributor and to the Medtronic contact provided on the verification form.

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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,
Medtronic GmbH

Enclosures:

- Attachment A
- Customer Acknowledgment Form

Attachment A:
IDENTIFYING AFFECTED PRODUCT
Locate product information on product labels in your inventory