Medtronic
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(Co.Reg.No. S98FC5604C)
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www.medtronic.com

URGENT: MEDICAL PRODUCT RECALL
Grafton™ DBM – Sterile Barrier Seal Issue

Affected Products:		
Grafton™ Putty	Grafton™ Matrix	Grafton™ DBF Inject
Grafton™ Crunch	Grafton™ Matrix Strips	Accelerate™ Grafton™ DBF
Grafton™ Flex	Grafton™ Plus Paste	Grafton™ Gel
Grafton™ Orthoblend	Grafton™ DBF	XPANSE™ Bone Insert

07 February 2023 | 16:24 SGT

Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear Risk Manager:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific serial numbers of Grafton™ DBM due to the potential for packaging non-conformances to Medtronic's specifications. Grafton™ DBM is packaged within a dual-barrier, sterile pouch packaging system. Non-conforming packaging may lead to a breach in the sterile barrier.

Issue Description:
In December 2022, Medtronic investigation concluded that during the packaging process, there was potential for the outermost Tyvek pouch and/or inner foil pouch to have been released with non-conformances to Medtronic specifications. Based on the current data, Medtronic calculates that due to this issue, approximately 1 in 208 (0.48%) affected products may have a compromised sterile barrier of the outermost Tyvek pouch. The inner foil pouch was also evaluated, and the probability of contamination of the Grafton product through both the Tyvek and inner foil pouch sterile barriers is deemed to be low. The probability of the Grafton product becoming contaminated, which can arise if both the inner and outer sterile barriers are breached, is less than 1 in 2.7 million.

If the outermost Tyvek pouch's sterile barrier is compromised, it may increase the risk of sterile field contamination. Sterile field contamination can lead to infection, which may require further medical intervention.

***Picture**: example of product packaged in inner foil pouch and outer Tyvek pouch.*

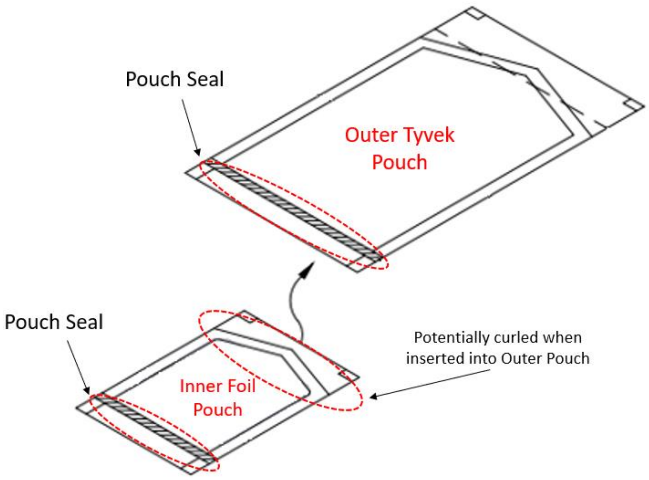

***Diagram**: image showing product packaging configuration (inner foil pouch sealed within outer Tyvek pouch)*

Through 10 January 2023, Medtronic has received five (5) reports that we have associated with this issue. There have not been any confirmed reports of patient harm attributed to this issue.

Products with a manufacture date after 30 November 2022 are not impacted. Product(s) manufactured prior to that date should be evaluated against the affected product list.

Required Actions:

Our records show that your facility has received the impacted product. Medtronic requests that you immediately take the following actions:

- Identify and quarantine any unused impacted product(s).
- NOTE: The following website can also be used to determine if specific product serial numbers are impacted: https://www.medtronic.com/graftonrecall. Returned product(s) will be inspected and re-released. The website will be updated regularly.
- Return the impacted product(s) to Medtronic by contacting your local Medtronic field representative.
- Complete the Customer Confirmation Form enclosed with this letter (even if you have no product to return), acknowledging that you have received this information.
- This notice should be distributed to all others in your organization who should be aware, or to any organization where the potentially affected devices have been transferred. Please maintain a copy of this notice in your records.

There are no actions required for patients where the affected products were used during a procedure. These patients should continue to be monitored as usual in accordance with standard care protocols.

Additional Information:

Grafton product inside the packaging has been manufactured and released in compliance with FDA requirements and passed all sterility testing at the time of manufacture.

Regulatory Notification:

Medtronic is communicating this information to the appropriate regulatory agencies. Adverse events or quality problems experienced with this product should be reported to your local Medtronic field representative.

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 field representative.

Sincerely,

DocuSigned by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 07 February 2023 | 16:23 SGT

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QARA Director

Southeast Asia and Frontier Markets Plus

Mainland and Island Southeast Asia

Enclosure:

- Customer Confirmation Form

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Customer Confirmation Form
URGENT: MEDICAL PRODUCT RECALL
Grafton™ DBM – Sterile Barrier Seal Issue

Please complete all fields below and return all pages immediately

Customer Contact Details	Medtronic Contact Details
Distributor/HCP/Patient name:	**Name:**
	Contact:
Address:	**Email:**
Phone no:	
E-mail:	

Even if you have no affected stock to be returned, please tick the appropriate box, and fill out the table below.

Do you have remaining inventory of the affected units? (Please select only ONE):

☐ no, **NONE** of the affected inventory to be returned. I have examined our inventory for product/s covered by this and confirm that all affected was/were previously consumed.

☐ **YES**, affected inventory to be returned. I have examined our inventory and have the affected product/s listed in the following table that remain/s unconsumed and is to be returned:

How did you purchase this product? (Please select only ONE):

☐ direct from Medtronic ☐ from a distributor [Distributor Name: _____]

Product Number / Item Code	Serial Number	Quantity (in eaches)

*If this table is not enough, please use the additional page provided. Additional page and/or attachments must be signed and dated.

By signing this form, I confirm that I have read the Urgent Medical Product Recall Notification Letter, dated 07 February 2023 | 16:24 SG **from Medtronic regarding Grafton™ DBM – Sterile Barrier Seal Issue and taken appropriate action.**

After completing the form, hand or scan then email it back to your local Medtronic field representative. For questions, contact your Medtronic Sales Representative.

Name (print): _____ Signature: _____ Stamp: _____ Date: dd Mmm yyyy

The addressee may continue to receive reminders of this notice until a response is received.

Use this page *****ONLY IF***** the space in the previous page is not enough.
Fill out the previous table first and list the remaining in this page.

This page must also be signed and dated.

Product Number / Item Code	Serial Number	Quantity (in eaches)

Name (print): _____ Signature: _____ Stamp: _____ Date: dd Mmm yyyy

The addressee may continue to receive reminders of this notice until a response is received.