Medtronic

Urgent Field Safety Notice

Durepair™ Dura Regeneration Matrix – all Lot numbers

Recall

June 2023

Medtronic Reference: FA1342

<For use in countries that follow EU MDR: EU Manufacturer Single Registration Number (SRN): US-MF-00001977>

Dear Customer/Distributor:

The purpose of this letter is to advise you that Medtronic is initiating a recall for all unexpired Durepair™ Dura Regeneration Matrix distributed prior to 22-May-2023.

Issue Description:

Medtronic was informed by the contract manufacturer (Integra LifeSciences Boston) that based on internal investigation they have identified issues with in-process and finished goods endotoxin testing. These issues may have resulted in the release of product with out-of-specification endotoxin levels. Due to this, Medtronic has voluntarily decided to recall all Durepair™ products manufactured at this Integra LifeSciences facility.

Through 23 May 2023, Medtronic has identified 18 complaints for Durepair™ that have been deemed potentially associated with this issue. While these complaints were not confirmed as associated with this issue, out of specification endotoxin levels could not be eliminated as a possible contributor to the reported events.

Patient care recommendations:

The presence of out of specification endotoxin levels may present clinically with signs and symptoms of an acute inflammatory process, comparable to infection. If a patient develops a reaction to endotoxins related to an affected implant, the reaction likely will manifest in the first few days to within a few weeks following surgery. For affected products that have been implanted, we recommend you monitor for any signs and symptoms of inflammation (fever, fluid collection, CSF drainage, meningismus) and complete any necessary medical testing or intervention. It remains important to rule out infection in patients presenting with signs and symptoms that could be associated with infection. Durepair™ products affected by this notification do not need to be explanted prophylactically.

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Product Scope:

Catalog Number	Description	Expiration date	GTIN
61100	DUREPAIR™ DURA SUBSTITUTE 2 X 2	On, or prior to, March 31, 2025	00643169063808
61105	DUREPAIR™ DURA SUBSTITUTE 3 X 3	On, or prior to, February 28, 2025	00643169063815
61106	DUREPAIR™ DURA SUBSTITUTE 1 X 3	On, or prior to, December 31, 2024	00643169063822
61110	DUREPAIR™ DURA SUBSTITUTE 4 X 5	On, or prior to, March 31, 2025	00643169063839
61111	DUREPAIR™ DURA SUBSTITUTE 1 X 1	On, or prior to, April 30, 2025	00643169063846

Actions:

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

- Immediately identify and quarantine unused affected products within your inventory. Refer to the table above for impacted products.
- Return all unused affected product(s) to Medtronic. Your Medtronic Sales Representative can assist in returning any affected product.
- Please complete the enclosed Customer Acknowledgement Form and email to <XXXXX>.
- 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 devices 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 representative at <XXXX>.

Sincerely,

Local / OU Manager