Medtronic

Urgent Field Safety Notice

Riptide™ Aspiration Tubing Incorrect Use-By Date

Model Number: MAT-110-110, GTIN 00763000300661 (Lot Numbers: 442711 & 442715)

Notification

November 2025

Medtronic Reference: FA1527

EU Manufacturer Single Registration Number (SRN): US-MF-000019796

Dear Valued Customer:

The purpose of this letter is to notify you about a labeling error associated two (2) lots of Riptide™ aspiration tubing (Model Number MAT-110-110); the lots are 442711 & 442715.

Issue Description:

Medtronic has identified the potential for incorrect use-by dates on the labeling of two (2) product lots. Devices from these products lots may contain incorrect use-by date on the pouch and/or the carton label, which is different from the true use-by date (3 years from the date of manufacture); reference Figure 1 below for image of incorrect use-by date on label. Through October 31st, 2025, Medtronic has received a total of five (5) complaints related to incorrect use-by date on label. Table 1 below outlines the manufacturing date and true use-by dates for these lots.

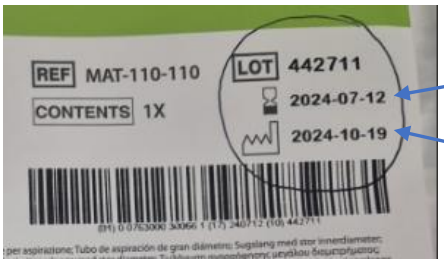

***Figure 1**: Image of incorrect use-by date '2024-07-12' on the label.*

Lot/Serial Number	Manufacturing Date (YYYY-MM-DD)	True Use-by Date (YYYY-MM-DD)
442711	2024-10-19	2027-10-19
442715	2024-10-22	2027-10-22

***Table 1**: Manufacturing and True Use-by Dates for impacted lots*

This issue does not pose a patient safety risk since the incorrect use-by date is sooner than the true use-by date and the impacted product lots are still within 3-year shelf-life period from the date of manufacture in October 2024.

Actions:

Our records show that your facility has received the impacted product. Please take the following steps:

1. Please note the true use-by dates for the impacted lots that are provided in Table 1 above. The products from the impacted lots are safe to use within the true use-by date and the customers may continue to use them until their true use-by date.
2. 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 and retain it with the affected product.

Medtronic anticipates a temporary supply disruption because of an on-going supplier manufacturing site transfer, unrelated to this issue. The customers may choose to continue using product from the impacted lots

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within their inventory until the true use-by date. Medtronic is actively collaborating with our suppliers to mitigate supply disruptions.

Regulatory notification

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,

Local / OU manager