Medtronic

Urgent Field Safety Notice

Torqr™ Diagnostic Catheters – Mislabeled catheters on outer box

Recall

Product Description	Model Number	UDI Number	Lot Number
Torqr™ Diagnostic Catheter 6 Fr OUS	041002JM	00643169883529	FA81265
	041005JM	00643169883567	FA81266

February 2025

Medtronic Reference: FA1471

EU Manufacturer Single Registration Number (SRN): US-MF-000019977

Dear Healthcare Professional/Risk Manager,

Medtronic is writing to inform you of incorrect outer box labeling for two manufactured lots of Torqr™ Diagnostic Catheter 6 Fr OUS ("Torqr") for the model and lot numbers listed above. Medtronic records indicate you have received at least one of the listed products. No other product model or lot numbers are affected by this action.

Issue Description:

Products associated with the models listed above have incorrect model and lot numbers on the outer box labeling. The inner pouch labels for all product in scope are accurate and only the outer box labeling is incorrect. A total of 48 units (24 units per lot) are affected. Affected product include two different model numbers of the Torqr, with the only difference between the models being the spacing of the distal electrodes. For detailed information, please refer to Table 1 below.

Table 1: Labeling Discrepancies

Correct Labeling	Actual Labeling (Discrepancy)
Outer box label REF: 041002JM LOT: FA81265 Distal electrode spacing: 2-5-2 mm	Outer box label REF: 041005JM LOT: FA81266 Distal electrode spacing: 5-5-5 mm
Outer box label REF: 041005JM	Outer box label REF: 041002JM

LOT: FA81266 Distal electrode spacing: 5-5-5 mm	LOT: FA81265 Distal electrode spacing: 2-5-2 mm

Up until January 13, 2025, Medtronic has received two (2) complaints related to this issue. There have been no reported adverse patient consequences associated with this issue. The mislabeled electrode spacing may cause a discernable difference in cardiac signal resolution. This could result in catheter replacement if the recording was deemed insufficient.

Patient Recommendations:

Patients previously supported with an impacted device face no additional risk from the issue described in this communication and should continue to be monitored per your practice's normal follow-up procedures.

Customer Actions:

Medtronic requests that you take the following actions:

- Review your inventory for listed product. Product is only mislabeled on the outer box label. The inner pouch label correctly identifies the packaged product. See Appendix A for an example of outer box labeling and location of REF and LOT number.
- Immediately identify and quarantine all unused, listed product in your inventory.
- Return unused, listed product in your inventory to Medtronic. Your Medtronic sales representative can assist you in the return of affected product as necessary.
- Complete the enclosed Customer Acknowledgement Form and email to <XXXX>. This form must be returned even if you do not have any affected product in your possession.
- Please share this notification with others in your organization as appropriate. If product listed above has been forwarded to another facility, please notify the facility of this Medtronic Urgent Field Safety Notice.
- Please maintain a copy of this communication in your records.

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

Enclosures:

- Appendix A: Example of outer box labeling of Torqr™ diagnostic catheters
- Customer Acknowledgement Form

Appendix A: Example of outer box labeling of Torqr™ diagnostic catheters

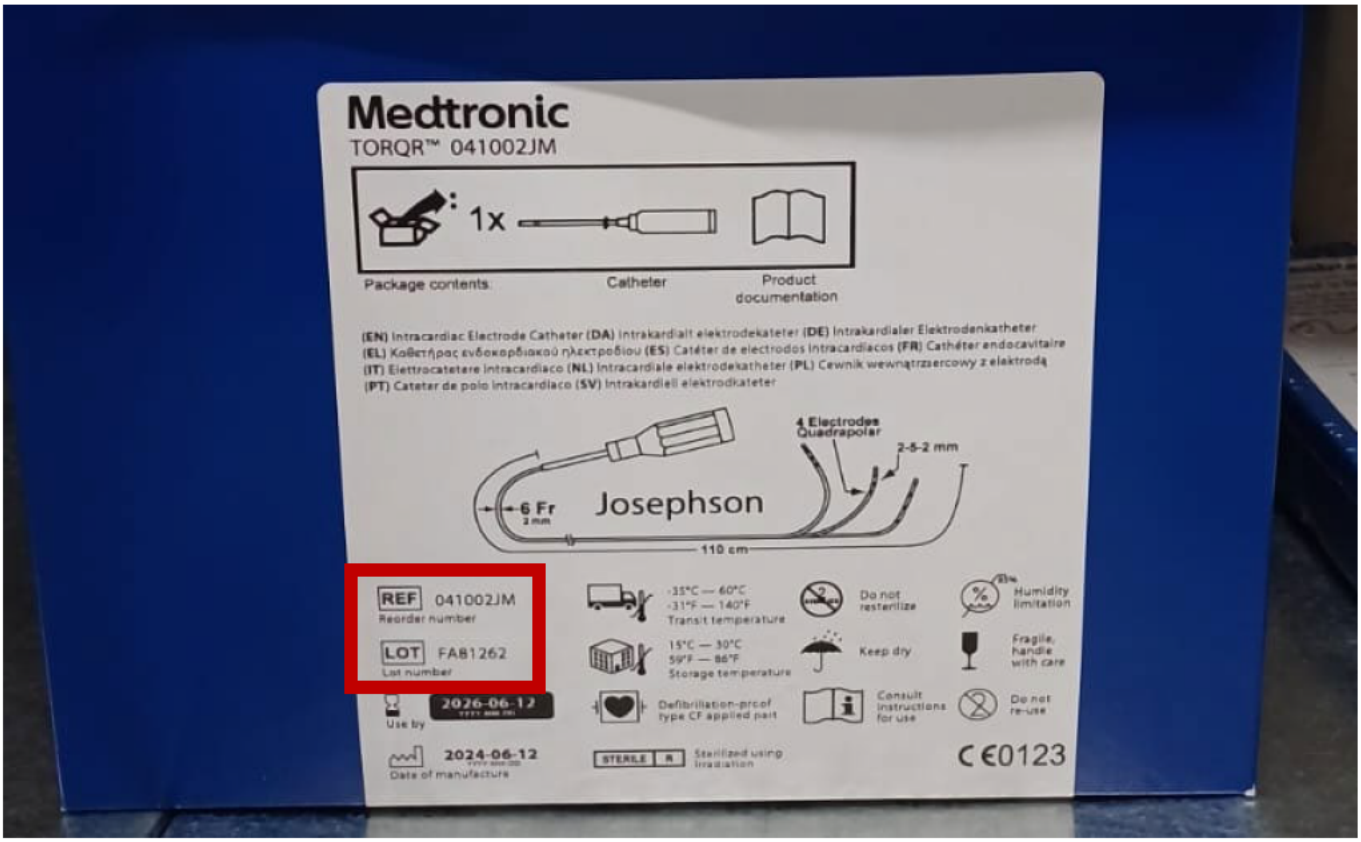

Figure 1: Outer box label of Torqr diagnostic catheter with location of REF and LOT number