Medtronic (Schweiz) AG
Weltpoststrasse 5
3015 Bern
www.medtronic.com

Urgent Field Safety Notice

Aortic Root Cannula – Excess Material

Recall

Product Description	Model Number
DLP™ Aortic Root Cannula	11014
MīAR™ Cannula	11012L
	11014L

February 2025

Medtronic Reference: FA1470

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

Dear HealthCare Professional/Risk Manager,

Medtronic notifies you of potential excess material in specific cannula product lots. Records show you received at least one affected lot number listed in Attachment A. No other models or lot numbers are affected.

Issue Description:

During the manufacturing process, unexpected loose material in the male luer used in the aortic root cannula was identified.

Up until January 10, 2025, Medtronic has received zero (0) complaints related to this issue. While there have been no observed events in the field, the potential for harm exists given the failure mode and the affected rate of 5% related to the identified scope. The potential harms when identified prior to use is procedure delay while another cannula is located. If this is not identified prior to use, and the clinician uses the cannula, the potential harms is stroke (reversible and irreversible).

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 using attachment A.
- Immediately identify and quarantine all unused, listed product in your inventory.
- Return unused, listed product in your inventory to Medtronic. Your Medtronic representative can assist you in the return of affected product as necessary.
- Complete the enclosed Customer Acknowledgement Form and email to rs.dusregulatory@medtronic.com. 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.

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.

Yours sincerely,
Medtronic (Schweiz) AG

Enclosures:

- Attachment A: Affected product and lot number
- Customer Acknowledgement Form

Attachment A – Affected product and lot number (in Switzerland)

DLP™ Aortic Root Cannula - CFN 11014				
2022070840	2023040435	2023060416	2024010419	2024030696
2022071072	2023060414	2023080116	2024030694	

MīAR™ Cannula - CFR 11012L				
2022010947	2022080414	2023070452	2023111072	2024040009
2022020084	2022090111	2023070458	2023111075	2024040041
2022040136	2022090112	2023070466	2023111279	2024040042
2022070051	2022090113	2023070954	2023111647	2024040043
2022070053	2022090828	2023070956	2024030803	2024050060
2022080060	2023021127	2023070962	2024040008	

MīAR™ Cannula - CFN 11014L				
2022030479	2022100742	2023040808	2023110253	2024030344
2022030748	2022100743	2023041173	2023110555	2024030981
2022070408	2022100744	2023050392	2023111652	2024030982
2022080061	2022100745	2023060119	2023120163	2024050387
2022080415	2022110715	2023060120	2024020446	2024050388
2022100741	2023020724	2023060233	2024020799	