Medtronic

# Urgent Field Safety Notice

## Arterial Cannulae – Mislabeled Cannulae

Recall

| Product Description | Model Number | Lot Number |
|---|---|---|
| DLP™ Pediatric One-Piece Arterial Cannulae | 77008 | 2024010723 |
| | | 202404C049 |
| | 77014 | 2023121097 |
| EOPA™ Arterial Cannula | 77422 | 2023020934 |
| | 77418 | 2022041038 |
| Select Series™ Angled Tip Arterial Cannula | 72422 | 2023071075 |
| | | 202309C075 |

December 2024

Medtronic Reference: FA1463
EU Manufacturer Single Registration Number (SRN): US-MF-000019977

Dear HealthCare Professional/Risk Manager,

Medtronic is writing to inform you of incorrect labeling for seven manufactured lots of Arterial Cannulae 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:**

During the manufacturing process of the seven specified lot numbers, products for the models listed above were incorrectly labeled with an incorrect size. Based on complaints received, Medtronic cannot determine the exact number of mislabeled units, but it is confirmed that at least one cannula from each of the listed lot numbers has been mislabeled. For detailed information, please refer to Figure 1 below.

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Figure 1: Labeling Discrepancies.

| Model # | Lot Number | Correct Labeling | Discrepancy |
|---|---|---|---|
| 77008 | 2024010723<br>202404C049 | Box should be: 77008<br>Pouch should be: 77008<br>Cannula should be: 8 Fr | Cannula might be: **16 Fr** |
| 77014 | 2023121097 | Box should be: 77014<br>Pouch should be: 77014<br>Cannula should be: 14 Fr | Cannula might be: **12 Fr** |
| 77422 | 2023020934 | Box should be: 77422<br>Pouch should be: 77422<br>Cannula should be: 22 Fr | Pouch might be: **77418** |
| 77418 | 2022041038 | Box should be: 77418<br>Pouch should be: 77418<br>Cannula should be: 18 Fr | Cannula might be: **22 Fr** |
| 72422 | 2023071075<br>202309C075 | Box should be: 72422<br>Pouch should be: 72422<br>Cannula should be: 22 Fr | Cannula might be: **24 Fr** |

As of November 1, 2024, Medtronic has received five (5) complaints related to this issue. There have been no reported adverse patient consequences associated with this issue. The potential harm when the mislabeling is identified prior to use is procedure delay while a correct cannulae size is located. In the event that a user did not identify the incorrect cannula prior to use, potential patient harms related to the use of an incorrectly sized cannula are Abrasion, Perforation, Hypovolemia and Hemolysis.

**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.
- 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.

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- This notice needs to 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 contact your Medtronic Representative.

Sincerely,

Local / OU manager