Medtronic (Schweiz) AG
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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.

Figure 1: Labeling Discrepancies.

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

- 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.
- 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,

Enclosures:

- Customer Acknowledgement Form

Medtronic

CUSTOMER ACKNOWLEDGEMENT FORM

Please email or fax this form back to Medtronic (even if you do not have affected inventory):

rs.dusregulatory@medtronic.com

Urgent Field Safety Notice - Recall

FA1463: Mislabeled Arterial Cannulae

Customer Contact Details			
Company name:			Account number (optional):
Address:		City:	Country:

- I confirm that I have read and understood the Urgent Field Safety Notice.
- I agree to pass on the Urgent Field Safety Notice to all those who need to be aware within our organization or to any organization where the potentially affected products have been transferred.
- I have reviewed our inventory, identified, and quarantined all unused affected products in our inventory, and I declare the following:

☐ No affected products are located at our facility.

☐ Affected products are located at our facility. See below table for details of affected products to be returned to Medtronic.

Name (print):	**Job title**:	**Date**:	**Signature**:

Please fill-in the section below only if you have affected stock:

Return Details			
Invoice or Delivery Note *(if available)*	**Item Code**	**Lot # / Serial #**	**Quantity** *(please count units inside of the box)*
☐ If you have more products to return, tick the box. Please create and send separate attachment with same data.			**Total**:

Contact Person at Point of Collection:		
Pick-up address / Department *(please provide location details. E.g.: collection/accessible area):*		
City:		Post code:
Pick-up phone number:	Pick-up email:	
When the product will be ready for pick-up? *(Please allow 2 days for handling your request):*		
Opening hours of the pick-up location:		Dimension LxWxH (in cm): … x … x …
# Pallets:	# Parcels:	Number of parcels weighing over 45 kg:

- Customer Service will contact you directly to organise return of affected products and credit will be given for returned products.
- Please don't send the goods back before having received the return documentation.
- Please package goods according to packaging instructions that will be provided upon confirmation & remove all labels from the inbound shipment.