**Sultanate of Oman**
**Ministry of Health**
**Drug Safety Center**
**Muscat**

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

**Circular No.** 11 / 2025

27 -07-1446 H
27 -01-2025

**Recall of EOPA™ Elongated One-Piece Arterial Cannula from Medtronic, Inc.**

| | |
|---|---|
| Source | SFDA- Saudi Food & Drug Authority.<br>https://ade.sfda.gov.sa/Fsca/PublishDetails/234 |
| Product | EOPA™ Elongated One-Piece Arterial Cannula. |
| Manufacturer | Medtronic, Inc. |
| Local agent | AL Zahrawi Medical Supplies. |
| The affected products | Product Description: EOPA™ Arterial Cannula.<br>Model Number: 77418.<br>Lot Number : 2022041038.<br><br>Correct Labeling: Box should be: 77418, Pouch should be: 77418, Cannula should be: 18 Fr.<br>Discrepancy: Cannula might be: 22 Fr. |
| Reason | Products for the models listed above were incorrectly labeled with an incorrect size. |
| Action | 1. Immediately identify and quarantine all unused, listed product in your inventory.<br>2. Return unused, listed product in your inventory to Medtronic.<br>3. Contact the local agent for remedial action. |
| comments | Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om |

**Dr. Mohammed Hamdan Al Rubaie**
**Director General**

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

**Sultanate of Oman**
**Ministry of Health**
**Drug Safety Center**
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سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

تقدم بثقة
Moving Forward with Confidence

رؤية عُمان 2040

**To:**
**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**
**Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)**
**Director General of Engineering Affairs, MOH**
**Director General of Royal Hospital**
**Director General of Khoula Hospital**
**Director General of Medical Supplies (MOH)**
**Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)**
**Hospital Director (Al Nahda Hospital)**
**Hospital Director (Al Massara Hospital)**
**The Head of Medical Services in SQU Hospital**
**The Head of Medical Services in Royal Oman Police**
**The Head of Medical Services in Ministry of Defence**
**The Head of Medical Services in The Diwan**
**The Head of Medical Services in The Sultan's Special Force**
**The Head of Medical Services in Internal Security Services**
**The Head of Medical Services in Petroleum Development of Oman**
**The Head of Medical Services in LNG Oman**
**ALL PRIVATE PHARMACIES & DRUG STORES**

**After Compliments,**

**Please find attached our Circular No** 11 **dated** 27/1/2025 **Regarding SFDA Recall of EOPA™ Elongated One-Piece Arterial Cannula from (mfr: Medtronic, Inc).**

**Copy to:**

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center

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ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Medtronic

# Urgent Field Safety Notice

## Arterial Cannulae - Mislabeled Cannulae

Recall

| Product Description | Model Number | Lot Number |
|---|---|---|
| EOPA™ Arterial Cannula | 77418 | 2022041038 |

December 2024

Medtronic Reference: FA1463

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 |
|---|---|---|---|
| 77418 | 2022041038 | Box should be: 77418<br>Pouch should be: 77418<br>Cannula should be: 18 Fr | Cannula might be: **22 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 nahar.s.alsurayi@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.

Medtronic

**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,

Hussein Khaldieh,
Operating Unit Manager

**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):

nahar.s.alsurayi@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.