Medtronic
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# URGENT: MEDICAL DEVICE CORRECTION

## DLP™ One-Piece Pediatric Arterial Cannula & Bio-Medicus™ Adult Cannula Kit

## Potential Product Contamination

| Product Description | Model Number | Lot Numbers |
|---|---|---|
| DLP™ One-Piece Pediatric Arterial Cannula | 77010 | 0231650870, C232227220 |
| Bio-Medicus™ Adult Cannula Kit | 96530-115 | 230257001 |

04 June 2026 | 00:49 CDT

Dear Healthcare Professional/Risk Manager,

The purpose of this letter is to advise you that Medtronic is initiating an Urgent Medical Device Correction involving specific lots of DLP™ One-Piece Pediatric Arterial Cannula and Bio-Medicus™ Adult Cannula Kit. Our records indicate that you have received product that is within the scope of this Urgent Medical Device Correction. Please note that no additional lot numbers are impacted by this communication.

**Issue Description:**

In April 2026, potential blood contamination was identified within sealed sterile packaging of cardiopulmonary bypass cannula products during the investigation of two complaint-returned devices: the DLP™ One Piece Pediatric Arterial Cannula (Model 77010) and the Bio-Medicus™ Adult Cannula Kit (Model 96530-115). In both instances, a small amount of loose foreign material was observed within the sterile packaging prior to use. Analysis of the returned products confirmed that the material contained trace levels of blood. No patients were exposed and no adverse clinical effects were reported. Refer to Attachment A for an image of the observed material.

As of April 8, 2026, Medtronic has received two (2) reports associated with this issue. Potential risks from direct contact with the blood contamination may include embolism, neurological dysfunction thromboembolism, organ dysfunction, biological reaction, infection and sepsis. Based on the two events observed with blood contamination, the likelihood of these events occurring is considered rare or highly unlikely.

**Patient Management Recommendations:**

Medtronic does not recommend any further actions for patients already supported with the listed devices and patients should be managed according to the standard of care after the procedure.

**Customer Actions:**

Medtronic requests that you take the following actions:

- Please do not open, handle, or use the affected product.
- Wear appropriate Personal Protective Equipment (PPE), such as gloves, to review your inventory for the listed lot numbers.
- If you have unused unit(s) from these lot numbers in your inventory, place the affected product, including packaging and Instructions for Use, in a clearly marked biohazard bag or container.
- Dispose of the biohazard material in accordance with your facility's procedures and all applicable local regulations for biohazardous waste.
- Complete the enclosed Customer Confirmation Form and return the completed form to your local Medtronic representative. A digital Customer Confirmation Form may also be completed using the QR code or link below.
- 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 Medical Device Correction.
- Please maintain a copy of this communication in your records.

**Digital Customer Confirmation Form:**

Link: https://na3.docusign.net/Member/PowerFormSigning.aspx?PowerFormId=ec1a2b3f-4aa2-46a0-96fb-b3501ea9c2c2&env=na3&acct=7a9c79df-7f8a-4520-aa76-f95b30782a76&v=2

**Additional Information:**

Medtronic is notifying the applicable regulatory authority of this issue.

Adverse reactions or quality problems experienced with this product should be reported to your local Medtronic representative.

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 local Medtronic representative.

Sincerely,

Signed by:
Siak Wah Yew
Signer Name: Siak Wah Yew
Signing Reason: I approve this document
Signing Time: 03 June 2026 | 22:45 PDT
99B5834721984194B5948835E56FD5D9

**Quality and Regulatory Affairs Lead**

Malaysia, Singapore, and Brunei

**Enclosures:**

- Customer Confirmation Form
- Attachment A: Images of the observed material

**Attachment A: Images of the observed material**

Figure 1: Foreign material located within the accessories pouch

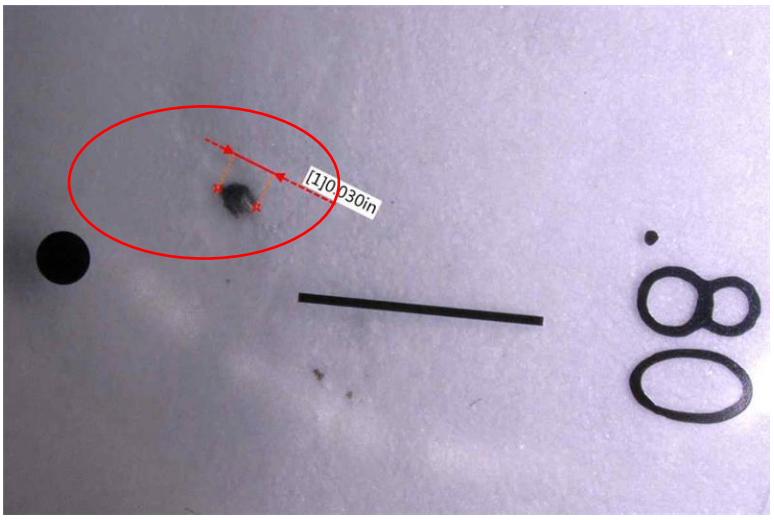


Figure 2: Expanded view of the foreign material within the accessories pouch

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**Customer Confirmation Form**

## URGENT: MEDICAL DEVICE CORRECTION

**DLP™ One-Piece Pediatric Arterial Cannula & Bio-Medicus™ Adult Cannula Kit**

**Potential Product Contamination**

***For completion by Medtronic Customers Only – Please complete all fields below and return immediately***

**I have read and understood the Urgent Medical Device Correction Notification Letter, dated** 04 June 2026 | 00:49 CDT **from Medtronic regarding DLP™ One-Piece Pediatric Arterial Cannula & Bio-Medicus™ Adult Cannula Kit Product Contamination and have followed the instructions as outlined in the Notification Letter.**

Please complete all fields and sign the form as indicated below. If you are completing the form manually, please return the completed form to your local Medtronic representative.

Hospital/Account Name _____

Hospital/Account Address _____

Country _____

First Name of Person Completing the form _____

Last Name of Person Completing the form _____

Title/ Department _____

Signature _____

Date _____

Medtronic Representative Name _____

Medtronic Representative Email Address *(optional)* _____

**Disposal Confirmation and Supporting Evidence**

☐ I have examined our inventory and confirm that all affected units were consumed prior to the receipt of this FCA notification. **No affected units remain in stock at this facility**.

☐ **All remaining unused affected units have been disposed of** in accordance with the hospital's biohazard procedures.

a) Quantity disposed and lot number(s): _____

b) Disposal evidence (may be provided to your local Medtronic representative or attached as file if signing the form digitally):

- ☐ Photo evidence
- ☐ Waste disposal record
- ☐ Certificate of destruction
- ☐ Others (please specify): _____
- ☐ Not available (please state reason): _____

If signing digitally, please upload the facility's disposal evidence here (if available):

For questions, please contact your local Medtronic Representative.

Note: The addressee may continue to receive reminders of this notice until a response is received.