Medtronic

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URGENT FIELD SAFETY NOTICE

EOPA™ Arterial Cannulae - Pinhole Leaks

Recall

Product Description	Model Number	GTIN-UDI
EOPA 3D® Arterial Cannula	*78222*	Refer to Attachment A
	78322	Refer to Attachment A
EOPA™ Elongated One-Piece Arterial Cannula	*77422*	Refer to Attachment A
	77522	Refer to Attachment A
	77622	Refer to Attachment A
	77722	Refer to Attachment A

June 2026

Medtronic Reference: FA1573

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

Dear Healthcare Professional/ Risk Manager,

The purpose of this letter is to advise you that Medtronic is initiating an Urgent Field Safety Notice involving specific lots of EOPA 3D® Arterial Cannulae and EOPA™ Elongated One-Piece Arterial Cannulae, specifically the 22 French (Fr) size. Our records indicate that you have received product that is within the scope of this Urgent Field Safety Notice. Please note that only the lot numbers listed in Attachment A are impacted by this communication.

Issue Description:

Medtronic received reports of pinhole leaks in the wire-wound body of 22 Fr EOPA 3D® Arterial Cannulae and EOPA™ Elongated One-Piece Arterial Cannulae used during cardiopulmonary bypass procedures. The leaks were identified either prior to use or during active bypass flow. No adverse patient outcomes have been reported. Evaluation of returned devices confirmed the presence of a small pinhole defect located near the 5th–6th spring wire coil beyond the final depth marking on the

cannula body. This condition may not be visible during routine inspection and is typically only detectable when the cannula is flexed.

Up until May 13, 2026, Medtronic has received 35 reports associated with this condition, representing an estimated occurrence rate of approximately 0.10%. Potential risks associated with this condition may include hypovolemia, vessel laceration or perforation, hypotension, ischemia, and organ dysfunction. No adverse patient outcomes have been reported.

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:

- Review your inventory for listed product using Attachment A.
- Immediately identify and quarantine all unused, listed product in your inventory.
- Return unused listed products to Medtronic. Your Medtronic sales representative can assist you in the return of unit as necessary.
- Complete and return the enclosed Customer Acknowledgment Form even if you do not have any affected products in your inventory, to acknowledge that you have read and understand this letter.
- Please share this notification with implanters and teams within your organization. If product listed above has been forwarded to another facility, please notify the facility of this Urgent Field Safety Notice.
- Please maintain a copy of this communication in your records.

Additional information:
This letter is also intended to notify you, in accordance with Article 10a, as introduced by Regulation (EU) 2024/1860, amending EU Medical Device Regulation 2017/745, that we anticipate a temporary interruption to the supply of EOPA 3D® Arterial Cannulae and EOPA™ Elongated One-Piece Arterial Cannulae, specifically the 22 Fr size, as a result of this recalling.

Medtronic expects to begin receiving initial recovery lots within the next 8-10 weeks, with full recovery expected between late September and early October 2026, depending on specific device production. Medtronic anticipates the need to place these devices on manual allocation. Products on manual allocation allow us to ship just in time and to ensure product gets to the hospital and, more importantly, the patients that need them.

It is anticipated that this temporary interruption of supply will occur from June through October 2026 for the following Model Numbers: 77422, 77522, 77622, 77722, 78222, and 78322. As an alternative during this period, customers may consider using the 20 Fr cannula, where clinically appropriate

however, availability for those models may also be limited. The corresponding Model Numbers for the 20 Fr devices are: 77420, 77520, 77620, 77720, 78220, and 78320.

Every effort is being made to resolve the temporary interruption of supply.

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 directly.

Sincerely,

Keith Taverner
Principal Regulatory Affairs Specialist UK & Ireland

Enclosed:

- Attachment A: Affected product and lot numbers
- Attachment B: Customer Acknowledgement Form
  Please See below:

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Attachment A – Affected product and lot numbers

Product Name	Model Number	GTIN	Lot Numbers			
CANNULA 77422 EOPA BLUNT 22FR	77422	00763000135638	0232446444	0232902697	0232985469	0233334923
			0232798353	0232902803	0233009922	
			0232895082	0232902846	0233127352	
		20763000135632	0232446429	0232601593	0232902697	0233108251
			0232446444	0232602180	0232902698	0233116991
			0232486752	0232798265	0232902700	0233127352
			0232601515	0232798353	0232902803	0233334923
			0232601516	0232849583	0232902805	0233334966
			0232601522	0232894981	0232902846	0233426694
			0232601586	0232895082	0232985469	0233426695
			0232601591	0232902694	0233009922	0233528727
CANNULA 77522 EOPA BLUNT 22FR	77522	00199150023288	0232745061	0232990983	0233286436	
		20199150023282	0232709428	0232862778	0232990983	0233553623
			0232744924	0232862794	0233286318	0233556386
			0232745061	0232862798	0233286414	0233585113
			0232745092	0232903216	0233286436	0233585114
			0232798556	0232903291	0233427120	0232670802
			0232862763	0232903383	0233528730	
CANNULA 77622 EOPA DIL TIP 22FR	77622	00763000135676	0233409034			
		20763000135670	0232601501	0232602290	0232910955	0233286374
			0232601510	0232602302	0233244075	0233286390
			0232601549	0232910952	0233244301	0233409034
			0232601550	0232910953	0233244531	0233416071
			0232602178	0232910954	0233286362	0233528731
CANNULA 77722 EOPA DIL TIP 22FR	77722	00199150023318	0232744945			
		20199150023312	0232657469	0232744945	0232862769	0233116924
			0232670800	0232798410	0232985251	0233116931
CANNULA 78222 EOPA 3D 22FR	78222	00763000135706	0232612916	0232709001		
		20763000135700	0232602300	0232708967	0232910882	0233245980
			0232602383	0232709001	0233077983	
			0232612916	0232910880	0233245850	
			0232680078	0232910881	0233245860	
CANNULA 78322 EOPA 3D 22FR	78322	00199150023257	0232862787			
		20199150023251	0232709184	0232798416	0232862787	
			0232745036	0232862784		

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CUSTOMER ACKNOWLEDGEMENT FORM

ATTACHMENT B

Medtronic Limited UK & IRE

Please email this form back to Medtronic (even if you do not have affected inventory): **rs.fsnuki@medtronic.com** within one week of receipt.

Urgent Field Safety Notice - Recall

FA1573: EOPA™ Arterial Cannulae – Pinhole Leaks

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)*

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☐ 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.