Medtronic

Medtronic Ireland Limited
3090-3094 Lake Drive
Citywest Business Campus
Dublin D24 NW2F
Ireland

Tel: 01 511 1400
Fax: 01 807 7220

www.medtronic.ie

Urgent Field Safety Notice

Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff Reusable Inner Cannula

Recall

Item Code	Product Description	GTIN	Affected Lot Numbers
7CN80R	Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff Reusable Inner Cannula	A8845212054401	202405258X
		20884521205441	
		10884521205444	

26th February 2025

Medtronic Reference: FA1480

EU Manufacturer Single Registration Number (SRN): US-MF-000028763

Dear Risk Manager, Directors of Respiratory Care, Anesthesiology, Pulmonary/Intensive Care and ENT:

The purpose of this letter is to advise you that Medtronic is issuing a recall of one lot of Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff Reusable Inner Cannula. This recall follows receipt of sixteen (16) reports from customers stating that the flange disconnected from the outer cannula of a device. Harms reported included respiratory failure, aspiration, unspecified tissue injury and/or a delay to treatment. You are receiving this letter because Medtronic records indicate that this device was shipped to your facility.

Issue Description:

Our investigation of the customer reports is on-going. Reports have only been received in relation to manufacturing lot 202405258X. To date, there is no indication that this issue impacts any other manufactured lots.

VAT: IE9513488W
Registered in Ireland No. 275799

Medtronic

Risk to Health:

Disconnection of the flange from the device cannula may result in respiratory failure, unspecified tissue injury, aspiration, respiratory tract infection, bronchospasm, a delay to treatment and/or death.

Patient Management:

For patients with the affected lot of Shiley™ Adult Flexible Tracheostomy Tubes with TaperGuard™ Cuff Reusable Inner Cannula (lot 202405258X) currently in place, a replacement is required. The patient's medical team should assess the overall patient risk when considering the timing of replacement. Clinicians should continue to follow current product Instructions For Use (IFU) along with facility specific policies and procedures.

Additional actions you should take:

- Quarantine all unused product from the affected lot of Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff Reusable Inner Cannula
- Return all unused product from the affected lot in your inventory to Medtronic as described on the Customer Acknowledgment Form.
- Pass on this notice to all those who need to be aware within your organization or to any organization where the potentially affected product from the specified lot has been transferred or distributed.
- Please complete and return the enclosed Customer Acknowledgment Form even if you **do not** have unused inventory.

Additional Information:

Medtronic has notified the Competent Authority of your country of this action.

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 at 01 511 1400

Sincerely,

Bethany Moxon
Associate Regulatory Affairs Specialist – UK and Ireland

Enclosures:
Attachment A: Identifying Potentially Affected Devices
Customer Acknowledgement Form

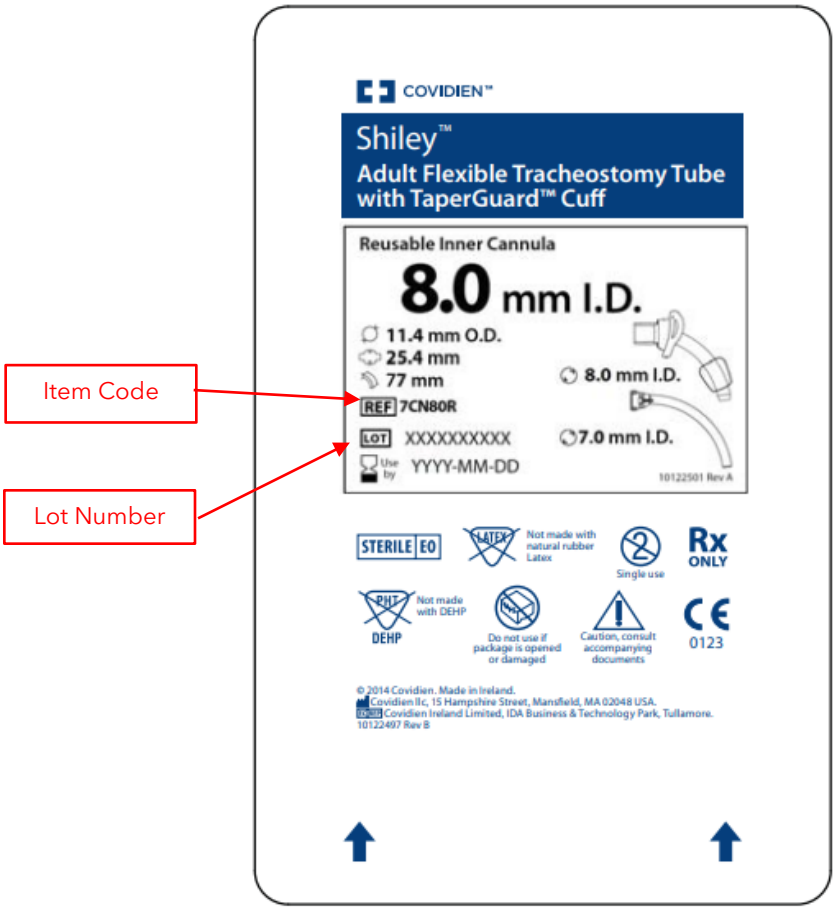
VAT: IE9513488W
Registered in Ireland No. 275799

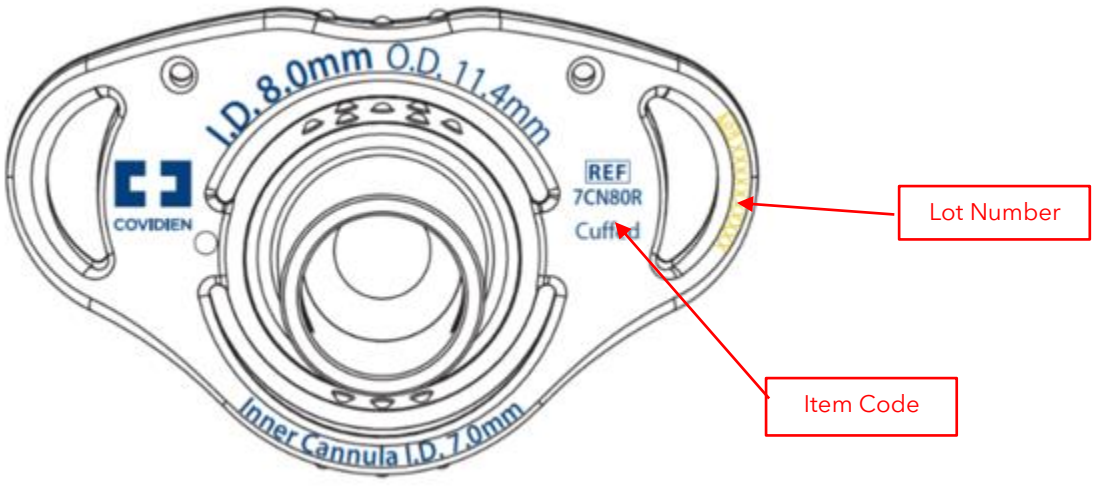
Medtronic

Attachment A:

IDENTIFYING POTENTIALLY AFFECTED DEVICES

Locate product information on product labels in your inventory.





VAT: IE9513488W
Registered in Ireland No. 275799

Medtronic

CUSTOMER ACKNOWLEDGEMENT FORM

Medtronic Ireland Limited
3090-3094 Lake Drive
Citywest Business Campus
Dublin D24 NW2F
Ireland

Tel: 01 511 1400
Fax: 01 807 7220

www.medtronic.ie

Please email or fax this form back to Medtronic (even if you do not have affected inventory): to rs.regulatoryuk-ire@medtronic.com

Urgent Field Safety Notice - Recall

FA1480 Shiley™ Adult Flexible Tracheostomy Tube Flange Disconnection from Cannula

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):*			

VAT: IE9513488W
Registered in Ireland No. 275799

Medtronic

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.

VAT: IE9513488W
Registered in Ireland No. 275799