



نتقدم بثقة
Moving Forward
with Confidence



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 60 dated 16/3/2025 Regarding SFDA Recall of Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff Reusable Inner Cannula from (mfr: Covidien llc).

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



Circular No. 60 / 2025

ننمذ بثقة
Moving Forward
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16 -09-1446 H
16 -03-2025

Recall of Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff Reusable Inner Cannula from Covidien llc.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/305
Product	Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff Reusable Inner Cannula.
Manufacturer	Covidien llc.
Local agent	AL Zahrawi Medical Supplies.
The affected products	Item Code:7CN80R. GTIN: A8845212054401, 20884521205441, 10884521205444. Affected Lot Numbers: 202405258X.
Reason	A potential disconnection of the flange from the device's outer cannula.
Action	1. Quarantine all unused product from the affected lot of Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff Reusable Inner Cannula. 2. Return all unused product from the affected lot in your inventory to Medtronic distributor. 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

Ph. Ibrahim Nasser Al Rashdi
Director General



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	

February 2025

Medtronic Reference: FA1480

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.

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.

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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 Medtronic Representative.

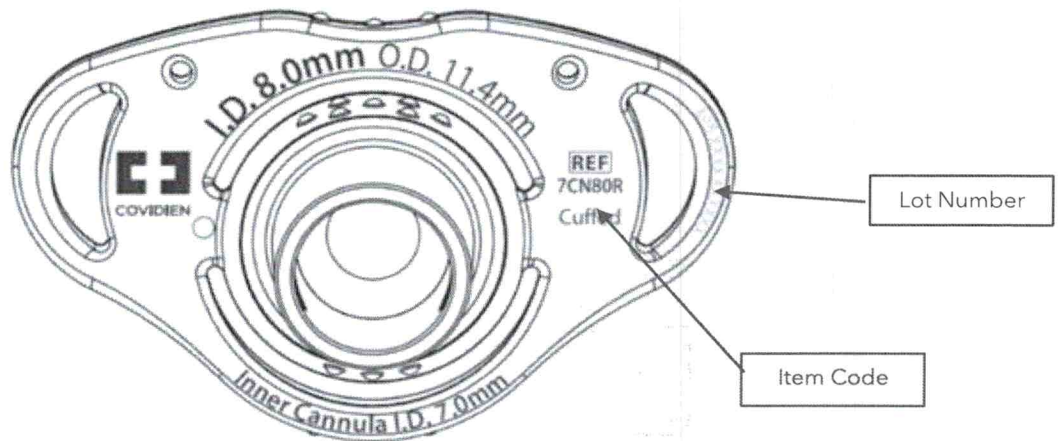
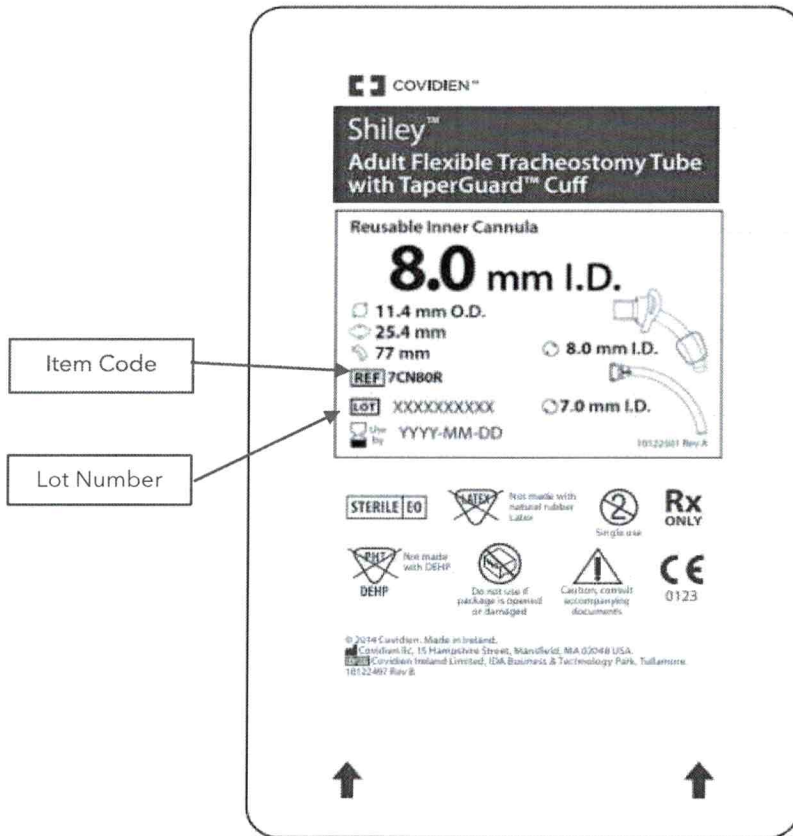
Sincerely,

Medtronic

Enclosures:

Attachment A: Identifying Potentially Affected Devices
Customer Acknowledgement Form

**Attachment A:
IDENTIFYING POTENTIALLY AFFECTED DEVICES
Locate product information on product labels in your inventory.**



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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

FA1480 Shiley™ Adult Flexible Tracheostomy Tube Flange Disconnection from Cannula

Customer Contact Details			
Company name:		Account number (optional):	
Address:		City:	Country:
<ul style="list-style-type: none">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: <input type="checkbox"/> No affected products are located at our facility. <input type="checkbox"/> 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)
<input type="checkbox"/> 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.