Medtronic

Urgent Field Safety Notice

Covidien DAR™ airway products

Recall

June 2021

Medtronic reference: FA975 phase II

Dear Customer.

As a follow-up to the Urgent Field Safety Notice Medtronic issued in April 2021, Medtronic is now issuing a market withdrawal in the European Economic Area (EEA) for specific production lots of its Covidien DAR™ airway products.

Issue Description:

Medtronic has concluded its investigation of potential deviations in the ethylene oxide sterilization processes performed by Steril Milano, the former supplier of our sterilization services for the DARTM airway products. Medtronic analyzed the available sterilization data and conducted validation tests on production lots where data was available. Our analysis concluded there was no quality issues for production lots where data was available. Where data was not available for our investigation, we have concluded that those specific production lots will be voluntarily recalled.

The withdrawal and recall actions affect item codes and lot numbers under quarantine at customer facilities in the EEA+CH+TR+UK as per April 2021 Medtronic communication. The products being withdrawn have no identified quality issues. Medtronic continues to work with our notified body and competent authorities in the EEA+CH+TR+UK to review the results of our investigation and analysis of the lots being withdrawn from the EEA+CH+TR+UK market.

Customers in the EEA +CH+TR+UK are requested to return all product currently under quarantine.

Required Actions:

- 1. Please immediately return to Medtronic all remaining product currently quarantined as a result of the April 2021 Urgent Field Safety Notice.
- 2. All unused products from the affected item codes and lots must be returned.
- 3. If you have distributed the DAR™ airway products, please promptly forward the information from this letter to those recipients.
- 4. Complete the Return Verification form even if you do not have inventory.

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased directly from Medtronic	Please complete the attached Returns Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to the Medtronic contact provided on the verification form.
Purchased from a distributor	Complete all fields on the form and contact your distributor directly to arrange for return of product.	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to your Distributor and to the Medtronic contact provided on the verification form.

Additional Information:

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

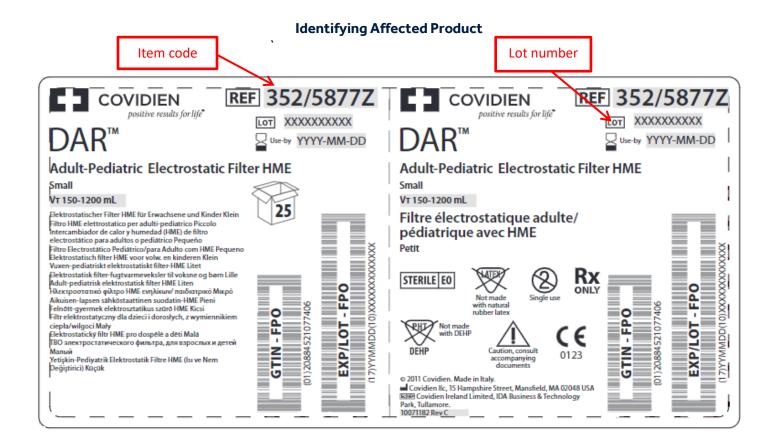
We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions, please contact your Medtronic Representative.

Sincerely,

Asi, Ala

Business Manager

Medtronic





RETURN VERIFICATION FORM

FA975 phase II: Covidien DAR™ airway products

Please complete this form and return it to Medtronic even if you do not have affected inventory

Customer Contact Details		Medtronic Contact D	Medtronic Contact Details	
Hospital Name		To:	1	
	tronic Account Number:		Medtronic APS RA Team	
Account Addre Street: Postal Code: City:	PSS:	Office 1, 12 Floor, A	Address: Office 1, 12 Floor, Abraj Al-Tawuniya, South Tower King Fahad Road, Olaya, Riyadh, Saudi Arabia	
Department: Contact Persor Opening Hours	n at Point of Collection: :: n completing this form:			
Telephone:	, , , , , , , , , , , , , , , , , , ,	Telephone: 0096650	Telephone: 00966503226812	
Fax:		Fax: NA	Fax: NA	
E-mail:		E-mail: nahar.s.alsu	E-mail: nahar.s.alsurayi@medtronic.com	
Item Code	Invoice or Despatch Note (if available)	Lot number	Quantity (Eaches or Cases) Please specify	
nformation for the cour Number of parcels to col				
Number of these parcels	s that weigh more than 45 KG:			
By signing this form, I co	onfirm that I have read and und	erstand the communication	from Medtronic regarding the Covidie	
DAR™ airway products	dated June 2021.			
	istribute and communicate this ovidien DAR™ airway products		n this letter to those whom I have	
Name: (print)	Signature:	Date:		
Dl f	sail thia farma ha aluta Madtuania.	within 10 days using the cente	act details referenced at the top of this	

- Please fax or email this form back to Medtronic within 10 days using the contact details referenced at the top of this
 form.
- 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.