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 DAR™ 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 The products being withdrawn have no identified quality issues.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authorities in the EEA + CH + TR + UK to review the results of our investigation and analysis of the lots being withdrawn from the EEA + CH + TR + UK market.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.

<table>
<thead>
<tr>
<th>Customer with inventory</th>
<th>Customer with zero inventory</th>
<th>Where to send the completed form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchased <strong>directly</strong> from Medtronic</td>
<td>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</td>
<td>Complete form and check the box indicating “no inventory”</td>
</tr>
<tr>
<td>Purchased from a <strong>distributor</strong></td>
<td>Complete all fields on the form and contact your distributor directly to arrange for return of product.</td>
<td>Complete form and check the box indicating “no inventory”</td>
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**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
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
Hospital Name: Covidien/Medtronic Account Number:

Medtronic Contact Details
To:
Medtronic APS RA Team

Account Address:
Street:
Postal Code:
City:
Department:
Contact Person at Point of Collection:
Opening Hours:
Name of person completing this form:

Address:
Office 1, 12 Floor, Abraj Al-Tawuniya, South Tower
King Fahad Road, Olaya, Riyadh, Saudi Arabia

Telephone:
Fax:
E-mail:

Telephone: 00966503226812
Fax: NA
E-mail: nahar.s.alsurayi@medtronic.com

Please list the quantity of affected product at your facility, if you have no inventory, please tick the box below.
No Inventory (Please tick): ☐

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Invoice or Despatch Note (if available)</th>
<th>Lot number</th>
<th>Quantity (Eaches or Cases) Please specify</th>
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Information for the courier:
Number of parcels to collect: __________________________
Number of these parcels that weigh more than 45 KG: __________________________

By signing this form, I confirm that I have read and understand the communication from Medtronic regarding the Covidien DAR™ airway products dated June 2021.

I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of the Covidien DAR™ airway products noted in this letter.

_________________________      _________________________________
Name: (print)                  Signature:                        Date:

• 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.