Medtronic

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URGENT MEDICAL DEVICE RECALL
Covidien GastriSail™ Gastric Positioning System

21 September 2017

Attention: Risk Management Director and O.R. Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling all production lots of its **Covidien GastriSail™ Gastric Positioning System**.

Issue Description:

This voluntary recall is being conducted following customer reports of esophageal or gastric perforations during bariatric procedures where the Covidien GastriSail™ Gastric Positioning System was used. Eighteen reports, representing 0.08% of devices, were received regarding this issue; many of these perforations were identified post-operatively. Medtronic engineering, quality and medical affairs team has not determined any device-related root cause for these reports. This voluntary recall affects the item codes and lots listed below.

Item Code	Item Description	Affected Lots	Expiration Date
GPS36	GastriSail™ Gastric Positioning System	All lots	September 2017 through May 2018
GPS40	GastriSail™ Gastric Positioning System	All lots	September 2017 through May 2018

Item Description	Affected Kit Parent Code				
Covidien™ Best Practices™ Endoscopic Procedure Kits containing GastriSail™ Positioning System	00Z2442	00Z2529	00Z2559	00Z2576	00Z2601
	00Z2476	00Z2575	00Z2568	00Z2580	00Z2643

Medtronic requests that you quarantine and return any unused products of the item codes detailed above. Unused products from the affected item codes should be returned as described in the Required Actions section below. If you have distributed Covidien GastriSail™ Gastric Positioning System listed above, please promptly forward the information from this letter to those recipients. All unused products from the affected item codes must be returned.

Required Actions:

1. Please quarantine and discontinue use of the affected item codes and lots listed.

2. Please complete the attached Recalled Product Return Form in its entirety. If you do not have any units from the affected lots in your inventory, simply tick "No affected inventory to be returned" and revert back to your local Medtronic Representative.

3. Please return affected product as follows:

- **CUSTOMERS WHO PURCHASED PRODUCT DIRECTLY FROM MEDTRONIC**

  Please complete the Covidien GastriSail™ Gastric Positioning System Recalled Return Form (attached) and return to your local Medtronic representative together with affected units if any.

- **CUSTOMERS WHO PURCHASED PRODUCT FROM A DISTRIBUTOR**

  Please complete the Covidien GastriSail™ Gastric Positioning System Recalled Return Form (attached) and contact your Distributor directly. All affected product and Recalled Product Return Form must be returned through the Distributor.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required. We request that you contact Medtronic if you experienced quality problems or adverse events.

If you have any questions or concerns regarding this recall, please do not hesitate to contact your local Medtronic representative.

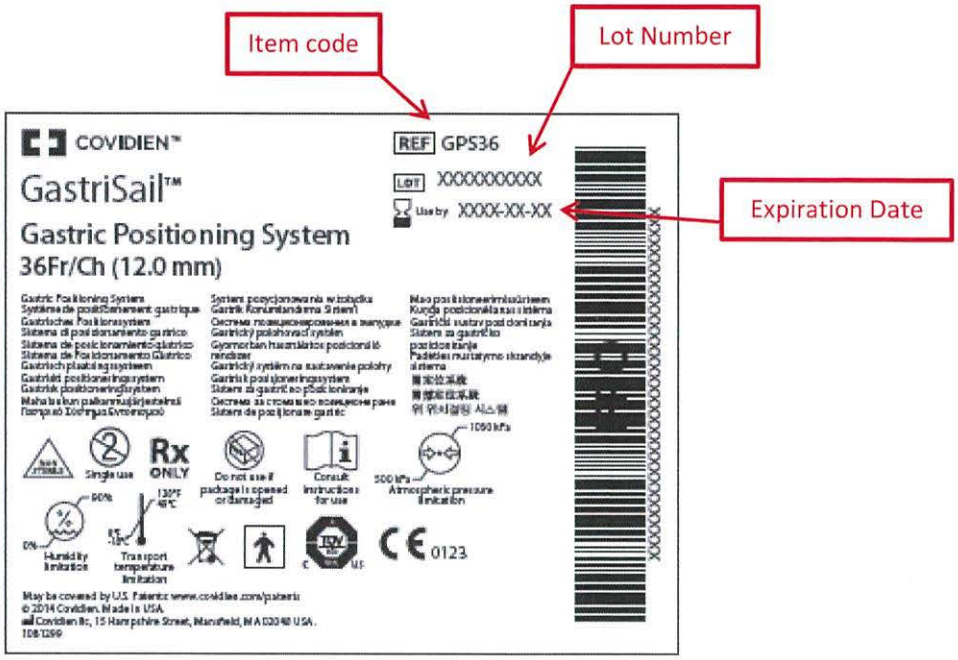
We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused.

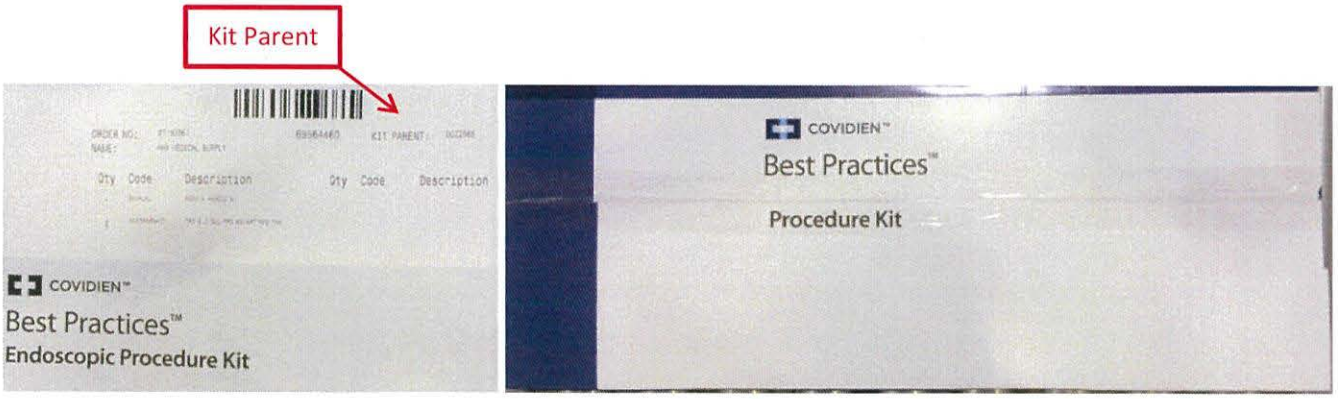
Sincerely,

[redacted]

Diana Teo
QA Supervisor
Medtronic

Attachment A





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RECALLED PRODUCT RETURN FORM
Covidien GastriSail™ Gastric Positioning System

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
Hospital / HCP:	**By E-mail:**
Address:	**By Post:**
Telephone no:	
Fax no:	
E-mail:	

Even if you have no affected stock to returned, please complete this form and table; return to your local Medtronic contacts stated above

Please tick (either one) only:

☐ No, no affected inventory to be returned.

☐ Yes, affected inventory to be returned (Please fill up the below table if chosen)

Item code	Product Description	Lot number	QTY (Each)

I have read and understand the instructions provided and acknowledge receipt of the Covidien Endo GIA™ Black Radial Reload with Tri-Staple™ Technology recall notification dated 14 September 2017 by signing below:

Name: _____ (print) Signature: _____ Stamp: _____ Date: _____