

URGENT FIELD SAFETY NOTICE
Covidien GastriSail™ Gastric Positioning System

September , 2017

Attention: Risk Management Director and O.R. Materials Management

Medtronic Reference: FA787

Dear Valued Customer:

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

Issue Description:

This Field Safety Corrective Action (FSCA) 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 FSCA affects the item code and lots listed below.

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

Medtronic requests that you quarantine and return any unused products of the item code detailed above. Unused products from the affected item code 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 code must be returned.

Required Actions:

1. Please quarantine and discontinue use of the affected item code listed on page one.
2. Please return affected product as indicated below.
3. Complete the Recalled Product Return 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 & to the Medtronic contact provided on the verification form.

This action is being taken with the knowledge of the [Insert name of local Competent Authority]. We request that you contact Medtronic if you experienced quality problems or adverse events.

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 regarding this communication, please contact your Medtronic representative at XXX-XXX-XXX.

Sincerely,



J. Bryan Dannettell
Vice President, Quality Assurance
Surgical Innovations Medtronic

Attachment A

COVIDIEN™
GastriSail™
Gastric Positioning System
36Fr/Ch (12.0 mm)

REF GP536
LOT XXXXX0000XX
Use by XXXX-XX-XX

Expiration Date

Item code

Lot Number

Non-STERILE
Single use
Rx ONLY
Do not use if package is opened or damaged
Consult instructions for use
500 kPa Atmospheric pressure limitation

Humidity limitation
Transport temperature limitation

May be covered by U.S. Patent: www.covidien.com/patents
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all Covidien Inc., 15 Hampshire Street, Mansfield, MA 02048 USA.
108-1299