

URGENT FIELD SAFETY NOTICE Covidien GastriSail™ Gastric Positioning System

September 25, 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.

Medtronic

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 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	<p>Please complete the attached Returns Verification Form in its entirety.</p> <p>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.</p>	Complete form and check the box indicating "no inventory"	E-mail the completed form to Audrey.doyle@medtronic.com .
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 Audrey.doyle@medtronic.com .

This action is being taken with the knowledge of the Irish Competent Authority, The Health Products Regulatory Authority (HPRA). 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 patricia.ramsbottom@medtronic.com.

Sincerely,



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



Audrey Doyle
RA Specialist

Attachment A

Item code

Lot Number

Expiration Date

COVIDIEN™

Gastrisail™

Gastric Positioning System
36Fr/Ch (12.0 mm)

REF GPS36
LOT XXXXXXXXXXXX
Use by XXXX-XX-XX

Gastric Positioning System
Système de positionnement gastrique
Gastriker Positioniersystem
Sistema di posizionamento gastrico
Sistema de posicionamiento gástrico
Sistema de Posicionamiento Gástrico
Gastričich položitel'nyj sistem
Gastričik položitel'nyj sistem
Gastričik položitel'nyj sistem
Mishalibun pal'ničnyj položitel'nyj sistem
Törpészék 36örményű évezényes
Sistema pozycjonowania żelazki
Gastrik Konstantleria Sistem
Qacrua no ampecepousea e nanyje
Gastričik položitel'nyj sistem
Gyomeiban használatos pozicionáló rendszer
Gastričik sistem na nastavenie položy
Gastričik položitel'nyj sistem
Sistema di gastrico posición
Qacrua di croua no ampecepousea pava
Sistema de posicionamento gástrico
Mao položitel'nyj sistem
Kao položitel'nyj sistem
Gastričik sistem položitel'nyj sistem
Sistema di gastrico posición
Položitel'nyj sistem
胃定位系统
胃定位系统
위 위치설정 시스템

1000 kPa
500 kPa
Atmospheric pressure
Indication

Single use
Rx ONLY
Do not use if package is opened or damaged
Consult instructions for use
Humidity indication
Transport temperature indication

CE 0123

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