Medtronic
60 Middletown Avenue
North Haven, CT 06473
www.medtronic.com

URGENT FIELD SAFETY NOTICE
Endo Peanut™ 5 mm Device

May, 2017

Medtronic reference: FA771

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

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is recalling specific production lots of its Covidien Endo Peanut™ 5 mm device.

Issue Description:

This Field Safety Corrective Action (FSCA) is being conducted following reports that the cotton tip of the device may disengage due to insufficient adhesive application during the manufacturing process. The use of products with this issue may increase the potential for the tip to disengage resulting in possible extension of operating room time or the need for unintended radiation exposure via x-ray for detection of the foreign body. While four (4) reports indicate that patients required an intraoperative x-ray to locate the disengaged tip, and in one case the tip was not retrieved subsequent to x-ray, no patient injury or impairment has been reported.

Medtronic requests that you quarantine and return any unused products of the items/lots detailed below (Refer to attachment A for details on affected procedure kits). Unused products from the affected item codes and lots should be returned as described in the Required Actions section below. If you have distributed the Endo Peanut™ devices listed below, please promptly forward the information from this letter to those recipients. All unused products from the affected item codes and lots must be returned.

Item Code	Item Description	Affected Lots	Expiration
173019	Endo Peanut™ 5 mm Device	M5K04X to M7A01X	October 2020 through to January 2022

This FSCA affects only the item code and lots listed above.

This action is being taken with the knowledge of the Competent Authority in your country. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. We request that you contact Medtronic if you experienced quality problems or adverse events.

- Email Medtronic Regulatory Affairs at: NordicRA@Covidien.com

Required Actions:

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

2. Please return affected product as follows:

	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.

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.

Sincerely,

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

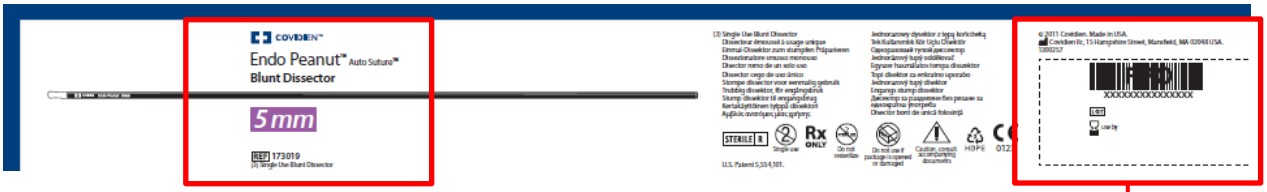
Sebnem Yavas Hoffsten
Regulatory Affairs Manager, Nordic Countries
Medtronic

Attachment A

Affected Kits Containing Endo Peanut™ Devices

Item Description	Affected Lots
KIT3049C PEIJAS BY-PASS KIT X1	0211439351
KIT3049C PEIJAS BY-PASS KIT X1	0211444522
KITM012 MOUNT VERNON TEP HERNIA X1	0211539264
KIT3049C PEIJAS BY-PASS KIT X1	0211551419
LAPCHOLE5S ZESTAW CHOLE 5 X1	0211745483
BOX KITLA0589	0211772886
LAPCHOLE5S ZESTAW CHOLE 5 X1	0211959271
KITM012 MOUNT VERNON TEP HERNIA X1	0211976428
KITM012 MOUNT VERNON TEP HERNIA X1	0212160033
LAPCHOLE5S ZESTAW CHOLE 5 X1	0212434205
BOX KIT3099A MEILAHTI GBP	0212556093
BOX KIT3099A MEILAHTI GBP	0212627653
BOX KIT00656R KIT BARIATRICA	0212743762
LAPCHOLE5S ZESTAW CHOLE 5 X1	0212775578
LAPCHOLE5S ZESTAW CHOLE 5 X1	0212886375
LAPCHOLE5S ZESTAW CHOLE 5 X1	0212921603
BOX KIT3099A MEILAHTI GBP	0212934908
BOX KIT3099A MEILAHTI GBP	0212971807
BOX KIT3099A MEILAHTI GBP	0213072366
KITM012 MOUNT VERNON TEP	S378269
KIT3096 GBP KIT MEILAHTI X1	S330944
KIT3049C PEIJAS BY-PASS KIT X1	S350018
KIT2912A FREDERICIA NEPHRECTOMY	S329302

Attachment B



COVIDIEN™

Endo Peanut™ Auto Suture™

Blunt Dissector

5 mm

REF 173019

(3) Single Use Blunt Dissector

U.S. Patent 5,554,161.

STERILE R Rx ONLY

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Covidien llc, 15 Hampshire Street, Mansfield, MA 02048 USA.

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LOT

Use by