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**URGENT: MEDICAL DEVICE RECALL**  
**Endo Peanut™ 5 mm Device**

9 May 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 specific production lots of its Covidien Endo Peanut™ 5 mm device.

**Issue Description:**

This voluntary recall 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. 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	2020-October through 2022-January

This voluntary recall affects only the item code and lots listed above.

### Required Actions:

1. Please quarantine and discontinue use of the affected item code and lots listed on Attachment A.
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 Recalled Product Return Form (attached) and return to your local Medtronic representative together with affected units if any.

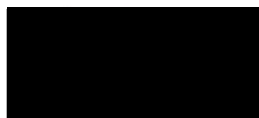
- **CUSTOMERS WHO PURCHASED PRODUCT FROM A DISTRIBUTOR**

Please complete the Recalled Product 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.

Thank you for your attention to this notification. We sincerely apologize for any inconvenience this situation may cause you or your facility.

Sincerely,



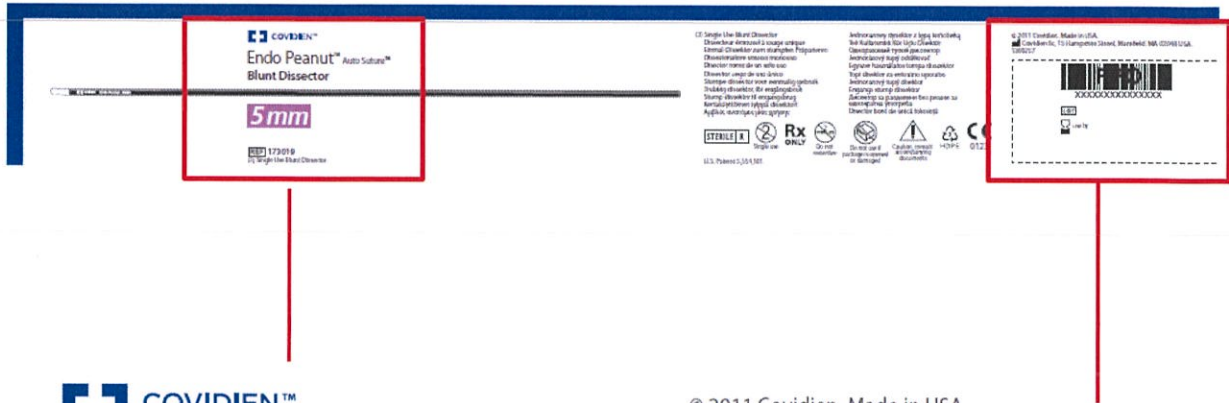
Diana Teo  
QA Supervisor, SEA  
Medtronic

**Attachment A**  
List of affected lots

Lot	Item #	Product Description
M5K04X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M5L01X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M5L02X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M5L03X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M5M01X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6A01X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6A02X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6A03X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6A04X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6B01X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6B02X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6B03X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6B04X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6C01X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6C02X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6C03X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6C04X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6C05X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6D01X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6D02X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6D03X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6D04X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6E01X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6E02X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6E03X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6E04X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)

Lot	Item#	Product Description
M6F01X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6F02X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6F03X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6F04X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6F05X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6G01X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6G02X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6H01X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6H02X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6H03X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6H04X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6J01X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6J02X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6J03X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6J04X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6K01X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6K02X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6K03X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6K04X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6L01X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6L03X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6L04X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6M01X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6M02X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M6M03X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)
M7M01X	173019	ENDO PEANUT* 5mm DEVICE (3 PER PACK)

## Attachment B



**Endo Peanut™ Auto Suture™**  
**Blunt Dissector**

**5mm**

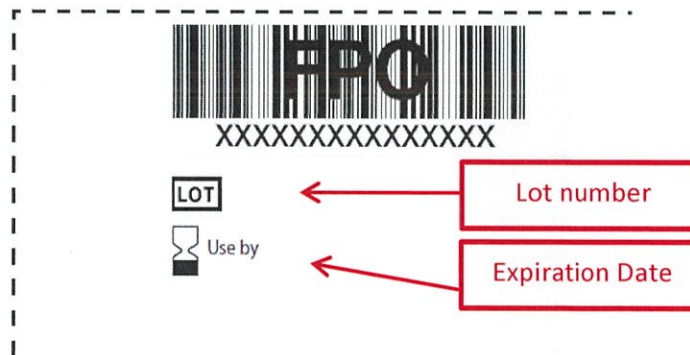
**REF 173019**

(3) Single Use Blunt Dissector

Item code

© 2011 Covidien. Made in USA.

Covidien Inc, 15 Hampshire Street, Mansfield, MA 02048 USA.  
1300257



Lot number

Expiration Date



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**RECALLED PRODUCT RETURN FORM**  
**Covidien Endo Peanut™ 5 mm Device**

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

Item Code	Product Description	Lot number	QTY (Each)

I have read and understand the instructions provided and acknowledge receipt of the Covidien Endo Peanut 5mm Device recall notification by signing below.

Name: \_\_\_\_\_ (print) Signature: \_\_\_\_\_ Stamp: \_\_\_\_\_ Date: \_\_\_\_\_