

## **MEDICAL DEVICE RECALL**

### **Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology**

26 December 2018

**Attention: OR Materials Management, Risk 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 issuing a voluntary recall for a specific item code and production lots of Covidien Emprint™ percutaneous antenna with Thermosphere™ technology. This voluntary action is being conducted as the devices that were distributed in Malaysia, Singapore, Thailand and the Philippines were not intended for those markets and do not meet local license registration requirements. There are no patient safety implications or quality issues related to this action.

This voluntary recall is in relation to the item codes and lots listed below.

Item Code	Description	Affected Lots		
CA15L1	Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology, Short (15 cm)	S7JG037LCX	S7KG001LCX	S8AG007CX

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

This action is being taken with the knowledge of local regulatory authorities. We request that you contact Medtronic if you experienced quality problems or adverse events.

#### **Required Actions:**

1. Please quarantine and discontinue use of the affected item codes and lots listed.
2. Please complete the attached Customer Confirmation 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 to your local Medtronic Representative.

3. Please return affected product as follows:

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

Please complete the Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology Customer Confirmation 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 Emprint™ Percutaneous Antenna with Thermosphere™ Technology Customer Confirmation Form (attached) and contact your Distributor directly. All affected product and Customer Confirmation Form must be returned through the Distributor.

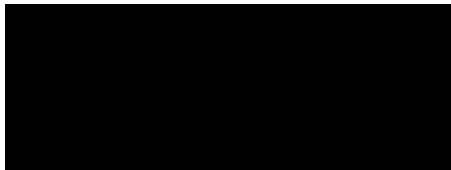
This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required. We request that you contact Medtronic if you experienced quality problems or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

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,



Diana Teo  
Quality Management System Manager  
South East Asia  
Medtronic

Item code

Lot number

**COVIDIEN**  
*positive results for life™*

**Emprint™**

Short Percutaneous Antenna with Thermosphere™ Technology  
1.5 cm

Antenne percutanée courte avec technologie Thermosphere™

Kurze perkutane Antenne mit Thermosphere™ Technologie

Antena percutanea corta con tecnologia Thermosphere™

Antenna percutanea corta con tecnologia Thermosphere™

Antena percutanea curta con tecnologia Thermosphere™

Kort perkutan anteni med Thermosphere™ teknologi

Korte perkutane antenne met Thermosphere™ technologie

Короткая перкусная антена с применением технологии Thermosphere™

採用 Thermosphere™ 技術的短針式天線

Krátká perkutánní anténa s technologií Thermosphere™

Kort, perkutan antenne med Thermosphere™ teknologi

Tehnoloogiat Thermosphere™ kasutav lühike perkutaanne anten

Thermosphere™-teknikkaa sisältävä lyhyt perkutaaninen antenni

Коротка перкутанна антена з технологією Thermosphere™

Βίολογία Thermosphere™ τεχνολογία περकुτανι αντεννα

짧은 경피 안테나(Thermosphere™ 기술 적용)

Trumpa perkutannine antena su Thermosphere™ tehnoloģija

Antenna Perkutanea Curta de Tecnologia Thermosphere™

Kort perkutan antenne med Thermosphere™-teknologi

Krótka elektrodna przeskórna z technologią Thermosphere™

Krátká perkutánná anténa s technológiou Thermosphere™

Thermosphere™-teknologija Kora Perkutan Anten

採用 Thermosphere™ 技術之短式針式天線

REF CA15L1

LOT 0000000X

Use by YYYY-MM-DD

STERILE EO Single use

Rx ONLY Do not resterilize

Consult instructions for use

Temperature limitations 149°F / 65°C

Keep dry

CE 0086

© 2013 Covidien. Made in China.  
Manufactured for Covidien Inc., 15 Hampshire Street, Mansfield, MA 02048 USA.  
Covidien Ireland Limited, IDA Business & Technology Park, Tullamore, I1909504

(01)10884521189539(17)YYMMDD(10)0000000X

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## Product Return Customer Confirmation Form **Emprint™ Percutaneous Antenna with Thermosphere™ Technology**

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
Hospital / HCP/Distributor:	Name:
Address:	Contact:
	Email:
Title:	
Direct Phone no:	
E-mail:	

**Even if you have no affected stock to returned, please acknowledge this form and 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 **Emprint™ Percutaneous Antenna with Thermosphere™ Technology** notification dated 26 December 2018 by signing below:

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