



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

**URGENT FIELD SAFETY NOTICE**

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

February XX, 2016

**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 item codes and production lots of Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology. This Field Safety Corrective Action (FSCA) is being conducted following customer reports of the Emprint™ ablation generator shutting down due to high temperature measurements in the Emprint™ Percutaneous Antenna. If the generator shuts down due to elevated temperature readings at the antenna tip, the antenna must be replaced and the ability to tract ablate is limited. Antenna replacement can result in a delay in treatment or the inability to treat and increases the risk of bleeding and, in the case of lung procedures, the occurrence of pneumothorax. There have been no reports of serious injury associated with this FSCA.

Medtronic is requesting that you quarantine any remaining inventory of the item codes and lot numbers detailed on Attachment A. Unused products from the affected item codes and lots should be returned as described in the Required Actions section below. If you have distributed Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology to other persons or facilities, please promptly forward the information from this letter to those recipients. All affected units must be returned.

This FSCA affects only the item codes listed below. Affected lots detailed on Attachment A. Lots numbers not included in Attachment A are not affected by this FSCA.

Item Code	Product Description
CA15L1	Covidien Emprint™ Short Percutaneous Antenna with Thermosphere™ Technology
CA20L1	Covidien Emprint™ Standard Percutaneous Antenna with Thermosphere™ Technology
CA30L1	Covidien Emprint™ Long Percutaneous Antenna with Thermosphere™ Technology

**Required Actions:**

1. Please quarantine and discontinue use of the affected item codes and lots listed on Attachment A.
2. Please return unused affected product as follows:

	<b>Customer with inventory:</b>	<b>Customer with Zero Inventory</b>	<b>Where to send the completed form</b>
Purchased <b>DIRECTLY</b> from Medtronic	Please complete the attached Returns Verification Form in its entirety and e-mail it to <local RA Mailbox> or fax to XXX.  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 <b>Distributor</b>	Complete <b>ALL</b> 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 Local Competent Authority Name).

If you are aware of any incidents related to this issue, please contact your local Medtronic Representative using the contact information detailed above to provide information regarding those events so regulatory reporting obligations can be fulfilled.

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative at XXX-XXX-XXX.

Sincerely,



David Cannistraci  
Vice President, Regulatory Affairs and Quality Assurance  
Early Technologies  
Minimally Invasive Therapies Group  
Medtronic

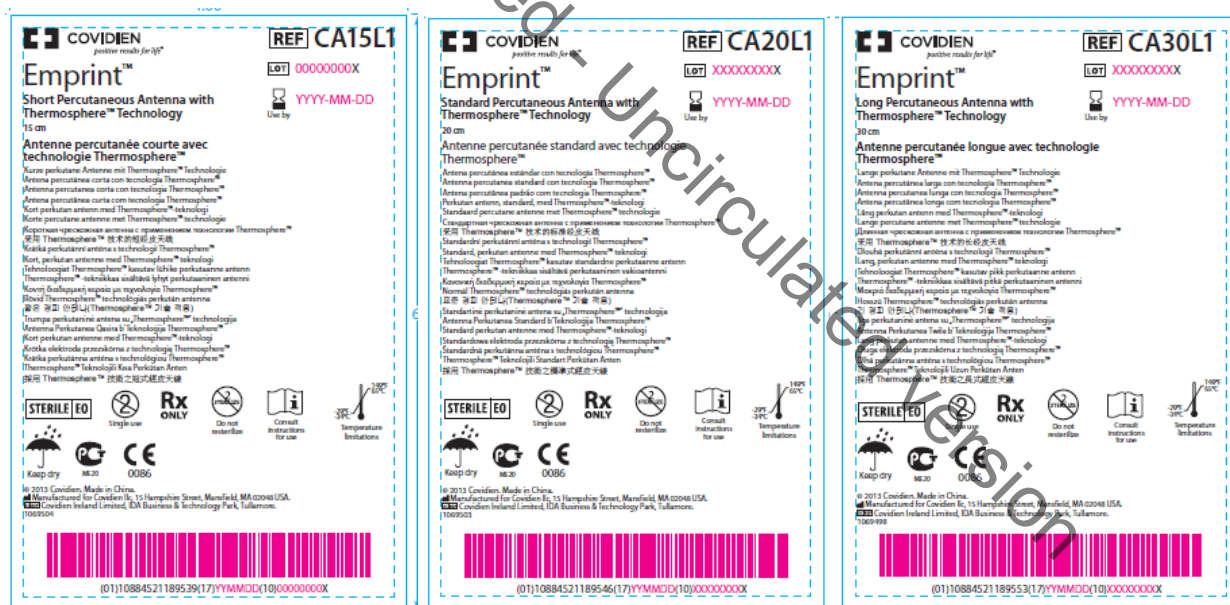
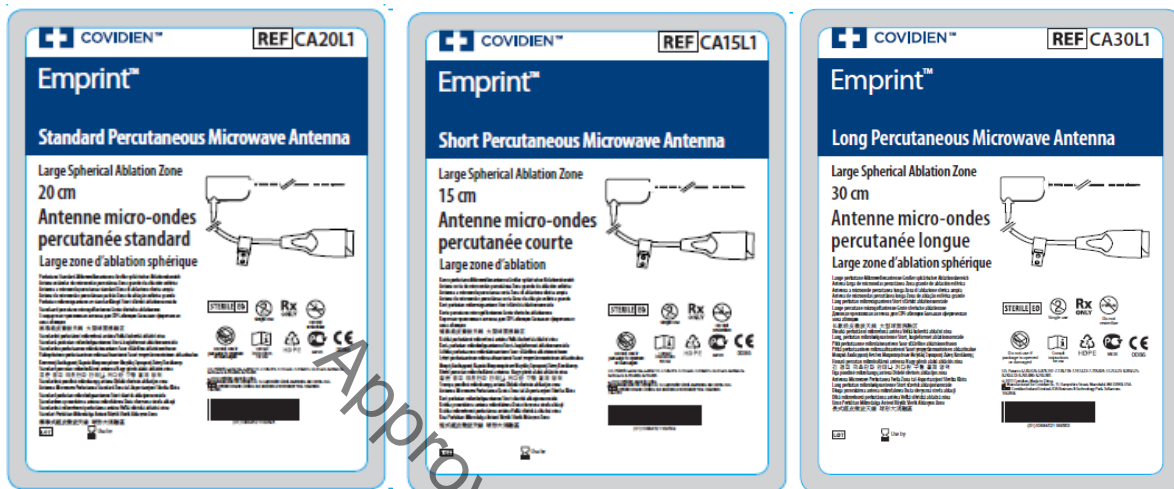
## Attachment A

### List of Affected Item Codes and Lot Number.

Item Code	Product Description					
<b>CA15L1</b>	<b>Covidien Emprint™ Short Percutaneous Antenna with Thermosphere™ Technology</b>					
<b>Affected Lot Numbers</b>						
S3MG004PRTX	S4HG001X	S4LG003PX	S4MG011PX	S5CG008X	S5GG002X	S5HG015X
S3MG005PRTX	S4HG002X	S4LG006LX	S4MG011QX	S5DG001X	S5GG004X	S5HG016X
S4BG001X	S4HG003X	S4LG006X	S4MG014QX	S5DG002X	S5GG005X	S5HG017RX
S4BG004X	S4HG004X	S4LG011LX	S5AG001PX	S5EG001X	S5GG009X	S5KG005X
S4DG001PX	S4HG005X	S4LG011X	S5AG003LRX	S5EG002X	S5GG012X	S5LG005X
S4EG003X	S4JG001X	S4LG012PX	S5AG005X	S5EG006X	S5GG013X	S5LG007X
S4EG007X	S4JG002X	S4LG012QX	S5AG007X	S5EG007X	S5HG001X	S5LG010X
S4EG008PRTX	S4JG003X	S4LG013PX	S5BG001LX	S5FG001X	S5HG002X	S5LG011X
S4FG003RX	S4JG004X	S4LG014PX	S5BG001RTX	S5FG002X	S5HG004X	S5LG013X
S4FG004X	S4JG005X	S4LG015X	S5BG001X	S5FG004X	S5HG005X	S5MG001X
S4FG007X	S4JG008X	S4MG001X	S5BG003RTX	S5FG006X	S5HG009X	S5MG003X
S4GG001X	S4KG002X	S4MG005X	S5CG001PX	S5FG007X	S5HG010X	S5MG006X
S4GG002X	S4KG003X	S4MG008PX	S5CG004X	S5FG009X	S5HG011X	
S4GG005X	S4LG002PX	S4MG009PX	S5CG005PX	S5GG001X	S5HG014PX	
<b>Item Code</b>						
<b>Product Description</b>						
<b>CA20L1</b>	<b>Covidien Emprint™ Standard Percutaneous Antenna with Thermosphere™ Technology</b>					
<b>Affected Lot Numbers</b>						
S4AG001PX	S4FG006X	S4KG007X	S4MG010PX	S5AG008RTX	S5EG004X	S5HG007X
S4BG002X	S4JG006QX	S4KG008QX	S4MG013PQX	S5AG008X	S5EG005X	S5KG001X
S4EG001PX	S4JG006X	S4KG008X	S4MG013PX	S5BG004RTX	S5FG008X	S5KG003X
S4EG002PX	S4JG007X	S4LG001PX	S5AG002QX	S5CG003X	S5GG003X	S5LG008X
S4EG006X	S4JG010X	S4MG002X	S5AG002X	S5CG006PX	S5GG011X	S5LG015X
S4FG001PRTX	S4KG001QX	S4MG003QX	S5AG006QX	S5DG003X	S5GG017X	S5LG016X
S4FG002RX	S4KG001X	S4MG003X	S5AG006RTX	S5DG004X	S5HG003X	S5MG002X
S4FG005X	S4KG007QX	S4MG010PQX	S5AG006X	S5EG003X	S5HG006X	
<b>Item Code</b>						
<b>Product Description</b>						
<b>CA30L1</b>	<b>Covidien Emprint™ Long Percutaneous Antenna with Thermosphere™ Technology</b>					
<b>Affected Lot Numbers</b>						
S3MG006PRTX	S4DG002PX	S4KG004X	S4LG010X	S5BG002RTX	S5GG014PX	S5JG001X
S3MG007PRTX	S4EG004X	S4KG006X	S4MG004X	S5BG002X	S5GG015PX	S5KG002X
S3MG008PRTX	S4EG005X	S4LG004X	S4MG012PX	S5CG002X	S5GG016PX	S5LG009X
S4BG003X	S4JG009X	S4LG005X	S5AG004X	S5CG007PX	S5HG008PX	S5MG007X
S4BG005PX						

Attachment B

Distinguish affected product by Item Code and Lot Number.



URGENT MEDICAL DEVICE Field Safety Corrective Action  
Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology

VERIFICATION FORM

**PLEASE COMPLETE THIS FORM IN ITS ENTIRETY**

**[Please insert date the form was sent]**

Customer Contact Details	Medtronic Contact Details
<b>Hospital Name:</b> <b>Covidien/Medtronic Account Number:</b>	<b>To:</b> [please insert name]
<b>Collection Address:</b> <b>Department:</b> Street: City: Postal Code: Contact Person at Point of Collection: Opening Hours:	<b>Address:</b> [please insert Medtronic address]
<b>Telephone:</b>	<b>Telephone:</b> [please insert Medtronic telephone number]
<b>Fax:</b>	<b>Fax:</b> [please insert Medtronic fax number]
<b>E-mail:</b>	<b>E-mail:</b> [please insert contact e-mail address]

**Item Codes: Refer to attachment A of the Urgent Field Safety Notice.**

Please list the quantity of affected product at your facility, if you have **no** inventory, please tick the box below.

**No Inventory (Please check):**

Item Code	Invoice or Despatch Note (if available)	Lot number	Quantity (Eaches or Boxes) Please specify

- Please complete this form and return it to Medtronic even if you have no affected inventory**

Information for the courier:

Number of parcels to collect: \_\_\_\_\_

Weight:  < 45kg       > 45kg

**By signing this form I confirm that I have read and understand the Urgent Field Safety Notice from Medtronic regarding-specific production lots of the Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology issued dated February, 2016**

<b><u>Customer Name: (Please Print)</u></b>	<b><u>Signature:</u></b>	<b><u>Date:</u></b>

- Please fax or email this form back to Medtronic within 10 days using the contact details referenced at the top of this form.
- Customer Service will contact you directly to organise return of affected products and credit will be given for returned products.
- Please don't send the goods back before having received the return documentation.
- **This action is being taken with the knowledge of the [add local Competent Authority].**

Approved - Uncirculated version