

# Medtronic

## Medtronic International, Ltd. (Singapore Branch)

(Co. Reg. No. S98FC5604C)

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### UPDATE

### Medical Device Safety Alert

### Instructions for Use Update: New Procedure Steps and Warnings

28 March 2019

**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 of an update to our 19 November, 2018, communication related to Medtronic's

**Covidien Emprint™ percutaneous and SX navigation antennas with Thermosphere™ technology.**

#### Reason for this notification

Medtronic will be updating the Instructions for Use (IFUs) for Emprint™ percutaneous antennas with Thermosphere™ technology to include important information identified through our investigation of detached antenna tips. Tip detachment during a procedure can lead to a retained foreign body, which creates risk for infection. The reported rate of detached tips is less than 0.05%. The IFU updates include important procedural steps and revised warnings to reduce the potential for antenna tip detachment.

#### Actions being taken by Medtronic

The IFUs for the devices listed below are being updated.

Item Code			Product Name
CA15L1	CA20L1	CA30L1	Emprint™ Percutaneous Antenna with Thermosphere™ Technology
CA15L2	CA20L2	CA30L2	
CA15L2N	CA20L2N	CA30L2N	Emprint™ SX Navigation Antenna with Thermosphere™ Technology

**The IFU updates are as follows:**

**Following Step 3, the update will be:**

**Warning**

*If using an accessory device to aid in the insertion of an antenna (example: cannula or needle guide), ensure that:*

- *The antenna shaft and tip are inserted through the accessory device without resistance or lateral force.*
- *The antenna shaft does not bend or scrape against the accessory device.*
- *The accessory device does not apply lateral force to the antenna.*
- *The green radiating section does not touch bare metal while energy is being delivered.*

*Failure to do so may:*

- *Cause damage to the antenna including breakage or detachment of the shaft and/or tip.*
- *Cause unintended thermal injury or alter the ablation pattern.*

**Step 5 Instruction Update**

*5. When energy delivery to the antenna stops, allow the pump to continue running for 5 seconds to cool the antenna. Then rotate the antenna shaft to release any adhered tissue. Then reposition or remove the antenna.*

**New Warning added following Step 5**

*Allow the antenna to cool as instructed in step 5 before repositioning or removing the antenna. This reduces the risk of antenna tip detachment.*

- The revised IFUs are expected to be distributed with Emprint™ devices beginning late Summer 2019.

**Actions you should take:**

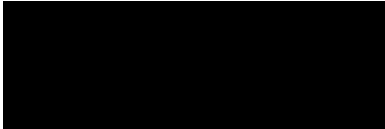
- Immediately notify all care environments in which the Emprint™ antennas are used about the IFU updates. You can continue to use Emprint™ antennas in accordance with the above guidance.
- If you have distributed any of the Emprint™ devices listed above, please promptly forward the information from this letter to those recipients.
- Complete the attached Customer Confirmation Form and return it as directed to confirm your receipt and understanding of this information.

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 any other quality problems or adverse events.

If you have any questions or concerns regarding this Field Action, 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 are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,



Diana Teo  
QRA Lead, SEA Country Cluster 1

Medtronic

*Enclosures: Customer Confirmation Form*

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**Update**  
**Medical Device Safety Alert**  
**Customer Confirmation Form — response is required**  
**Covidien Emprint™ percutaneous and SX navigation antennas**  
**with Thermosphere™ technology**

**ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY**

Customer Contact Details	Medtronic Contact Details
Physician / HCP/Distributors :	Name:
	Contact:
Address:	Email:
Phone no:	
E-mail:	

I have read and understand the instructions provided and acknowledge receipt of the Medical Device Safety Alert regarding the Emprint™ percutaneous and SX navigation antennas with thermosphere™ Technology by signing below.

I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of the Emprint™ devices listed above.

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

If you have any questions regarding this Medical Device Safety Alert, please contact your Medtronic sales representative.

