

Urgent Field Safety Notice

Instructions for Use Update: New Procedure Steps and Warnings Covidien Emprint™ Percutaneous Antennas with Thermosphere™ Technology

April 2019

Medtronic reference: FA781 - IFU update

Dear Physician or Healthcare Professional,

The purpose of this letter is to advise you that 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 relevant departments in which the Emprint™ antennas are used about the IFU updates. You can continue to use Emprint™ antennas in accordance with the above guidance.

The Competent Authority of your country has been notified of this action. Please maintain a copy of this notice in your records. We request that you contact Medtronic if you experienced quality problems or adverse events.

We regret any inconvenience this may cause. If you have any questions regarding this communication, please contact your Medtronic representative at 01 511 1400.

Sincerely,



Samantha Baxter
Regulatory Affairs Manager
UK and Ireland