

**URGENT FIELD SAFETY NOTICE**  
**Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology**

August 2017

**Attention: Risk Management Director and O.R. Materials Management****Medtronic Reference: FA781**

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling all Covidien Emprint™ Percutaneous Antennas with Thermosphere™ Technology.

**Issue Description:**

This Field Safety Corrective Action (FSCA) is being conducted following six (6) customer reports of the ceramic trocar tip of the Emprint™ ablation antenna disengaging from the needle shaft post-ablation. Tip disengagement can result in the ceramic trocar tip remaining in the patient presenting a risk of latent migration and potential damage to adjacent tissue. Four of the complaint reports indicate that the trocar tip was not retrieved.

This FSCA affects only the item code and lots listed below.

Item Code	Product Description	Item Code	Product Description	Lots beginning with	Expiration Date
CA15L1	Emprint™ Percutaneous Antenna with Thermosphere™ Technology, Short (15 cm)	CA15L2	Emprint™ Percutaneous Antenna with Thermosphere™ Technology – Reinforced Antenna, Short (15 cm)	S5L through S7G	November 2017 through July 2019
CA20L1	Emprint™ Percutaneous Antenna with Thermosphere™ Technology, Standard (20 cm)	CA20L2	Emprint™ Percutaneous Antenna with Thermosphere™ Technology – Reinforced Antenna, Standard (20 cm)		
CA30L1	Emprint™ Percutaneous Antenna with Thermosphere™ Technology, Long (30 cm)	CA30L2	Emprint™ Percutaneous Antenna with Thermosphere™ Technology – Reinforced Antenna, Long (30 cm)		

Medtronic is requesting that you quarantine any remaining inventory of the item codes detailed above. Unused products from the affected item codes should be returned as described in the Required Actions section below. If you have distributed the Covidien Emprint™ Percutaneous Antenna devices affected by this recall to other persons or facilities, please promptly forward the information from this letter to those recipients. All units must be returned.

**Required Actions:**

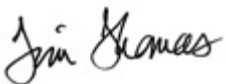
1. Please quarantine and discontinue use of the affected item codes and lots listed on page one.
2. Please return affected product as indicated below.

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased <b>directly</b> from Medtronic	Please complete the attached Returns Verification Form in its entirety. 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 name of local Competent Authority]. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. We request that you contact Medtronic if you experienced quality problems or adverse events.

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,



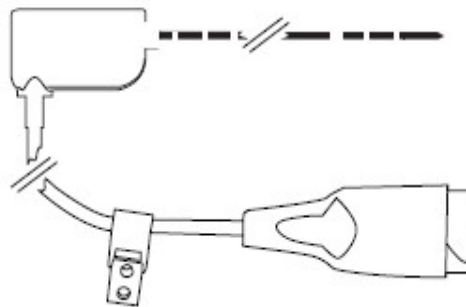
Timothy Thomas  
 Vice President, Regulatory Affairs and Quality Assurance  
 Early Technologies  
 Minimally Invasive Therapies Group  
 Medtronic


**COVIDIEN™**
**REF** CA15L1
Item #

# Emprint™

## Short Percutaneous Microwave Antenna

**Large Spherical Ablation Zone**  
**15 cm**  
**Antenne micro-ondes**  
**percutanée courte**  
**Large zone d'ablation**



Kurze perkutane Mikrowellenantenne Großer sphärischer Ablationsbereich  
 Antena corta de microondas percutánea Zona grande de ablación esférica  
 Antenna a microonde percutanea corta Zona di ablazione sferica ampia  
 Antena de microondas percutanea curta Zona de ablacao esférica grande  
 Kort perkutan mikrovågstantenn Stort sfäriskt ablationsområde  
 Korte perkutane microgolfantenne Grote sferische ablatiezone  
 Короткая чрезкожная антенна для СВЧ-абляции Большая сферическая зона абляции  
 短款经皮微波天线 大型球面消融区  
 Krátká perkutánni mikrovlnná anténa Veľká kulovitá ablačná zóna  
 Kort, perkutan mikrobølgeantenne Stort, kugleformet ablationsområde  
 Lühike perkutaanne mikrolaineantenn Suur sfääriline ablaatsioonitsoon  
 Lyhyt perkutaaninen mikroaalloantenni Suuri ympyrämuotoinen ablaatioalue  
 Μικρή Διαδερμική Κεφαλή Μικροκυμάτων Μεγάλη Σφαιρική Ζώνη Καύσεως  
 Rövid perkutan mikrohullámú antenna Nagy gömb alakú ablációs zóna  
 짧은 경피 극초단파 안테나 커다란 구형 열제 영역  
 Trupna poodine mikrobangu antena Didelė sferinės abliacijos zona  
 Antenna Microwave Percutanea Qasira Zona tal-Asportazzjoni Sferika Kbira  
 Kort perkutan mikrobølgeantenne Stort sfærisk ablasjonsområde  
 Krótka przezskórna antena mikrofalowa Duża sferyczna strefa ablacji  
 Krátká mikrovlnová perkutánná anténa Veľká sférická ablačná zóna  
 Kısa Perkütan Mikrodalgı Anteni Büyük Sferik Ablasyon Zonu  
 短式經皮微波天線 球形大消融區

**STERILE EO**       **Rx ONLY**       **Do not sterilize**  
 Single use  
      
 Do not use if package is opened or damaged      Consult instructions for use      HDPE      ME20      CE 0086

U.S. Patents 6,582,426; 6,878,147; 7,128,739; 7,147,632; 7,318,824; 7,527,623; 8,280,525; 8,282,632; 8,292,880; 8,292,881.  
 © 2013 Covidien. Made in China.  
 Manufactured for Covidien LLC, 15 Hampshire Street, Mansfield, MA 02048, USA.  
 Covidien Ireland Limited, IDA Business & Technology Park, Tallamore, 1062789



Lot

 → LOT

 Use by

