

**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 Saudi Food and Drug 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 [mohamed.el-ghor@medtronic.com](mailto:mohamed.el-ghor@medtronic.com).

Attachment A



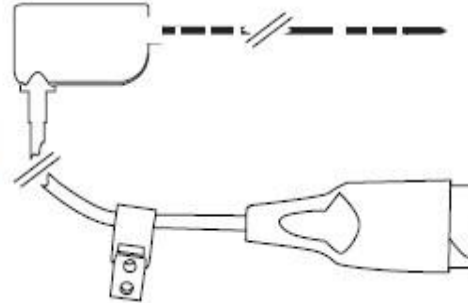
Item #

# 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 percutánea curta Zona de ablação esférica grande  
Kort perkutan mikrovågsantenn Stort sfäriskt ablationsområde  
Korte perkutane mikrogolfantenne Grote sferische ablatiezone  
Короткая чрескожная антенна для СВЧ-абляции Большая сферическая зона абляции

短軟経皮微波天线 大型球面消融区  
Krátká perkutánni mikrovlnná anténa Velká kulovitá ablační zóna  
Kort, perkutan mikrobølgeantenne Stort, kugleformet ablationsområde  
Lühike perkutaanne mikrolaineantenn Suur sfääriline ablatsoonitsoon  
Lyhyt perkutaaninen mikroaaltantenni Suuri ympyränmuotoinen ablaatioalue  
Μικρή Διεργητική Κεφαλή Μικροκυμάτων Μεγάλη Σφαιρική Ζώνη Κατάλυσης  
Kısa Perkutan Mikrodalgası Anteni Büyük Küresel Ablasyon Bölgesi  
Trupna poodine mikrobangy antena Didelė sferinė abliacijos zona  
Antenna Microwave Percutanea Qasira Zona tal-Asportazzjoni Sferika Kbira  
Kort perkutan mikrobølgeantenne Stort sfærisk ablasjonsområde  
Krátká průzkumná anténa mikrovlnová Dužá sferyczna strefa ablacji  
Krátká mikrovlnová perkutánná anténa Velká sférická ablační zóna  
Kisa Perkutan Mikrodalga Anteni Büyük Sferik Ablasyon Zonu  
短式経皮微波天线 球形大消融區



U.S. Patents 6,582,426; 6,878,147; 7,128,739; 7,147,632; 7,318,804; 7,527,623; 8,280,525; 8,282,632; 8,292,890; 8,292,881.  
© 2013 Covidien. Made in China.  
Manufactured for Covidien Inc., 15 Hampshire Street, Mansfield, MA 02048, USA.  
Covidien Ireland Limited, IDA Business & Technology Park, Tullamore, 1062789



(01)10884521169539

Lot → LOT

Use by