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**URGENT MEDICAL DEVICE RECALL**  
**Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology**

8 August 2017

**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 that Medtronic is voluntarily recalling all Covidien Emprint™ Percutaneous Antennas with Thermosphere™ Technology.

**Issue Description:**

This voluntary recall 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 voluntary recall 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.
2. Please complete the attached Recalled Product Return Form in its entirety. If you do not have any units from the affected lots in your inventory, simply tick “No affected inventory to be returned” and revert back to your local Medtronic Representative.
3. Please return affected product as follows:

- **CUSTOMERS WHO PURCHASED PRODUCT DIRECTLY FROM MEDTRONIC**

Please complete the Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology Recalled Return Form (attached) and return to your local Medtronic representative together with affected units if any.

- **CUSTOMERS WHO PURCHASED PRODUCT FROM A DISTRIBUTOR**

Please complete the Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology Recalled Return Form (attached) and contact your Distributor directly. All affected product and Recalled Product Return Form must be returned through the Distributor.

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 quality problems or adverse events.

If you have any questions or concerns regarding this recall, 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.

Sincerely,



Diana Teo  
QA Supervisor  
Medtronic



REF CA15L1



Item #

Emprint™

# Short Percutaneous Microwave Antenna

Large Spherical Ablation Zone

15 cm

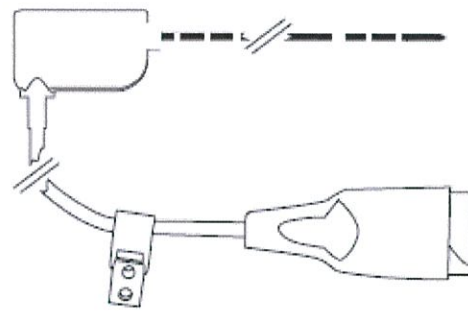
Antenne micro-ondes  
percutanée courte

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 percutánea curta Zona de ablação esférica grande  
Kort perkutan mikrovågstantenn Stort sfäriskt ablationsområde  
Korte perkutane microgolfantenne Grote sferische ablatiezone  
Короткая переконная антенна для СВЧ-абляции Большая сферическая зона абляции

短款经皮微波天线 大型球面消融区

Krátká perkutánní mikrovlnná anténa Velká kulovitá ablační zóna  
Kort, perkutan mikrobølgeantenne Stort, kugleformet ablationsområde  
Lühike perkutaanne mikrolaineantenn Suur sfääriline ablaatsioonitsoon  
Lühyt perkutaaninen mikroaaltotantenni Suuri ympyränmuotoinen ablaatioalue  
Μικρή Διαδερμική Κεφαλή Μικροκυμάτων Μεγάλη Σφαιρική Ζώνη Καύσης  
Rövid perkutan mikrohullámú antenna Nagy gömb alakú ablaációs zóna  
짧은 경피 극초단파 안테나 커다란 구형 열제 영역  
Trumpa poodinē mikrobandu antena Didelē sfēriskā ablaācijas zona  
Antenna Microwave Percutanea Qasira Zona tal-Asportazzjoni Sferika Kbira  
Kort perkutan mikrobølgeantenne Stort sfærisk ablaasjonsområde  
Krátká przezskórna antena mikrofalowa Duża sferyczna strefa ablacji  
Krátká mikrovlnová perkutánná anténa Velká sférická ablační zóna  
Kusa Perkütan Mikrodalga Anteni Büyük Sferik Ablasyon Zonu  
短式經皮微波天線 球形大消融區



STERILE EO



Single use

Rx ONLY



Do not sterilize



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 Inc, 15 Hampshire Street, Mansfield, MA 02048, USA.  
Covidien Ireland Limited, EOA Business & Technology Park, Tullamore, 1062700



(01)10884521189539



LOT



Use by



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**RECALLED PRODUCT RETURN FORM**  
**Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology**

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

Customer Contact Details	Medtronic Contact Details
<b>Hospital / HCP:</b>	<b>By E-mail:</b>
<b>Address:</b>	<b>By Post:</b>
<b>Telephone no:</b>	
<b>Fax no:</b>	
<b>E-mail:</b>	

**Even if you have no affected stock to returned, please complete this form and table; return to your local Medtronic contacts stated above**

Please tick (either one) only:

- No, no affected inventory to be returned.
- Yes, affected inventory to be returned (Please fill up the below table if chosen)

Item code	Product Description	Lot number	QTY (Each)

I have read and understand the instructions provided and acknowledge receipt of the Recall regarding Covidien Emprint™ Percutaneous Antenna devices dated 8 August 2017 by signing below:

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