

## **UPDATED**

### **URGENT FIELD SAFETY NOTICE**

#### **Covidien Emprint™ Percutaneous Antennas with Thermosphere™ Technology.**

November 2018

Medtronic reference: FA781

**Attention: Risk Management Director, Interventional Radiology Director, O.R. Materials Management**

Dear Valued Customer:

The purpose of this letter is to advise you of an update to our August 2017 communication related to Medtronic's voluntary recall of specific production lots of its Covidien Emprint™ Percutaneous Antennas with Thermosphere™ Technology.

Additional lots of the three codes listed below have been added to this recall. A list of the additional affected product is contained in Attachment A of this letter.

#### **Issue Description:**

This expansion of our voluntary recall is being conducted following receipt of seven (7) customer reports of the ceramic trocar tip of the Emprint™ ablation antenna disengaging from the antenna shaft during patient procedures. Tip detachment during the procedure can lead to a retained foreign body, which creates risk for infection. Five of the complaint reports indicate that the trocar tip was not retrieved during the primary procedure. Patients with a known retained ceramic trocar tip should be monitored by their care team for signs and symptoms of infection.

This voluntary recall update affects only the item codes and the lot numbers listed on Attachment A.

<b>Item Code</b>	<b>Product Description</b>	<b>Affected Lots</b>
CA15L2	Emprint™ Percutaneous Antenna with Thermosphere™ Technology – Reinforced Antenna, Short (15 cm)	See Attachment A
CA20L2	Emprint™ Percutaneous Antenna with Thermosphere™ Technology – Reinforced Antenna, Standard (20 cm)	
CA30L2	Emprint™ Percutaneous Antenna with Thermosphere™ Technology – Reinforced Antenna, Long (30 cm)	

**Required Actions:**

1. Please immediately quarantine and discontinue use of the affected item codes and lots listed on Attachment A.
2. Please return affected product as indicated below.
3. If you have distributed Emprint™ Percutaneous Antennas with Thermosphere™ Technology listed on Attachment A, please promptly forward the information from this letter to those recipients.
4. Complete the Recalled Product Return Form **even if you do not have inventory**.

	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.

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 apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative.

Sincerely,



Subu Mangipudi  
 Vice President, Quality  
 Respiratory, Gastrointestinal and Informatics  
 Minimally Invasive Therapies Group  
 Medtronic

**Attachment A**  
**List of Affected Lots for Updated Action**

Item Code	Product Description	Affected Lot Number				
CA15L2	Emprint™ Percutaneous Antenna with Thermosphere™ Technology – Reinforced Antenna, Short (15 cm)	S7HG002X	S7JG011X	S7KG039X	S7MG020X	S8CG019PX
		S7HG003X	S7JG033LX	S7KG040X	S7MG021X	S8CG022PX
		S7HG005KX	S7JG034X	S7KG042X	S7MG022PX	S8CG025X
		S7HG006KX	S7JG035X	S7LG001X	S7MG023PX	S8DG014LX
		S7HG022LX	S7JG041LX	S7LG002X	S7MG024X	S8DG015LX
		S7HG023LX	S7JG042LX	S7LG006X	S7MG025X	S8DG016LX
		S7HG024LX	S7JG043LX	S7LG011X	S7MG026X	S8DG017LX
		S7HG025LX	S7JG044LX	S7LG012X	S8AG001X	S8DG018LX
		S7HG029LX	S7JG045LX	S7MG008LX	S8AG002X	S8DG024X
		S7HG040X	S7JG046LX	S7MG009LX	S8AG011X	S8DG027X
		S7HG041X	S7JG047LX	S7MG011X	S8AG013X	S8EG005X
		S7HG045X	S7KG023LX	S7MG012X	S8CG004X	S8EG009X
		S7HG049X	S7KG029X	S7MG014X	S8CG010X	S8EG010X
		S7JG007X	S7KG033X	S7MG018X	S8CG017X	S8EG011X
CA20L2	Emprint™ Percutaneous Antenna with Thermosphere™ Technology – Reinforced Antenna, Standard (20 cm)	S7HG001PX	S7HG039LX	S7KG009LX	S7MG017PX	S8CG018X
		S7HG004KX	S7HG042LX	S7KG010LX	S7MG029X	S8CG023X
		S7HG010KX	S7HG043X	S7KG041X	S8BG001X	S8DG019LX
		S7HG011KX	S7JG006X	S7KG043X	S8BG002X	S8DG020LX
		S7HG012KX	S7JG010X	S7LG003X	S8BG006X	S8DG021LX
		S7HG030LX	S7JG013X	S7LG004X	S8CG001X	S8DG022LX
		S7HG031LX	S7JG014X	S7MG003X	S8CG008LX	S8DG023X
		S7HG035LX	S7KG008LX	S7MG004LX	S8CG009X	S8DG025X
CA30L2	Emprint™ Percutaneous Antenna with Thermosphere™ Technology – Reinforced Antenna, Long (30 cm)	S7HG007KX	S7HG033LX	S7JG012X	S7MG010LX	S8CG002X
		S7HG008KX	S7HG034LX	S7KG012LX	S7MG019X	S8DG001X
		S7HG009KX	S7JG008LX	S7KG038QX	S8BG004X	S8DG026X
		S7HG032LX	S7JG009X	S7LG009X	S8BG005X	S8EG004X

Item code



REF CA15L2

Emprint™

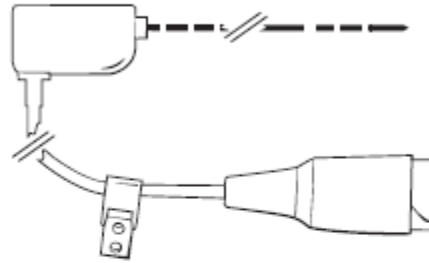
Short Percutaneous Antenna with Thermosphere™ Technology

Large Spherical Ablation Zone - Reinforced Antenna  
15 cm

Antenne percutanée courte avec technologie Thermosphere

Large zone d'ablation sphérique - antenne renforcée

Antena percutănea curta com tecnologia Thermosphere  
Zona de ablação esférica de grande porte - antena reforçada  
Kurze perkutane Antenne mit Thermosphere Technologie  
Großer sphärischer Ablationsbereich - Verstärkte Antenne  
Antena percutănea curta con tecnologia Thermosphere  
Zona grande de ablação esférica - Antena reforçada  
Antenna percutanea corta con tecnologia Thermosphere  
Zona di ablazione sferica ampia - Antenna rinforzata  
Korte perkutane antenne met Thermosphere technologie  
Grote sferische ablatiezone - Versterkte antenne  
Kort perkutan antenn med Thermosphere-teknologi  
Stort sfærisk ablationsområde - Forstærkt antenn  
Короткая чрескожная антенна с применением технологии Thermosphere  
Большая сферическая зона абляции - усиленная антенна  
采用 Thermosphere 技术的短经皮天线  
大型球面消融区 - 增强天线  
Kısa percutan antena s teknolojia Thermosphere  
Широка сферична зона за аблация - подсилена антена  
Krátká perkutání anténa s technologií Thermosphere  
Velká kulovitá ablační zóna - zesílená anténa  
Kort, perkutan antenne med Thermosphere-teknologi  
Stort, kugleformet ablationsområde - forsterket antenne  
Tehnologiat Thermosphere kasutav lühike perkutaanne antenn  
Suur sfääriline ablaitsioonitsoon - tugevdatud antenn  
Thermosphere -teknoloogias sisalduv lyhyt perkutaaninen antenni  
Suuri ympyrämuotoinen ablaatioalue - vahvistettu antenni  
Κοινή διασφαιική κεφαλή με τεχνολογία Thermosphere  
Μεγάλη σφαιρική ζώνη καύσης - Ενισχυμένη κεφαλή  
Krátka perkutana antena za navođenje s Thermosphere tehnologijom  
Velika sferna zona ablacije - pojačana antena  
Thermosphere tehnologija rvid perkutan antena  
Nagy, gömb alakú ablaációs zóna - Megerősített antenna  
짧은 피부 경유 안테나 (Thermosphere 기술 적용)  
커다란 구형 절제 영역 - 강화 안테나  
Isa perkutana antena ar Thermosphere tehnologiju  
Liela sfēriska ablaācijas zona - pastiprināta antena  
Trupna perkutaninė antena su Thermosphere technologija  
Dielē sfērisk ablaācijas zona - sustiprināta antena  
Antenna Percutanea Curta b/Tecnología Thermosphere  
Zona tal-Asportazzjoni Sferika Kbira - Antenna Rinforzata  
Kort perkutan antenne med Thermosphere-teknologi  
Stort sfærisk ablaationsområde - Forsterket antenne



Krátká elektroda prazeskóma w technologi Thermosphere  
Duza sferyczna strefa ablacji - wzmacniona elektroda  
Krátká perkutáná anténa s technologií Thermosphere  
Velká sférická ablační zóna - zesílená anténa  
Krátká antena za perkutano uporabo s tehnologijo Thermosphere  
Veliko območje sferične ablacije - ojačana antena  
Krátka perkutana antena sa Thermosphere tehnologijom  
Velika sferna zona ablacije - pojačana antena  
Antenă scurtă pentru intervenție percutanată cu tehnologie Thermosphere  
Regiune de ablație sferică mare - antenă reforțată  
Thermosphere Tehnologiji Kisa Perkutan Anten  
Büyük Sferik Ablasyon Zona - Güçlendirilmiş Anten  
採用 Thermosphere 技術之經皮下短式天線  
大型的半圓球狀消融區 - 強化天線



May be covered by U.S. Patent: [www.covidien.com/patents](http://www.covidien.com/patents)  
© 2016 Covidien. Made in China.  
Manufactured for Covidien Inc., 15 Hampshire Street, Mansfield, MA 02048 USA.  
Covidien Ireland Limited, IGA Business & Technology Park, Tullamore, F1000-0760



Lot number printed here