

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

19 November 2018

Attention: Risk Management Director and O.R. Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

The purpose of this letter is to advise you of an update to our August 7, 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.

Item Code	Product Description	Affected Lots
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 quarantine and discontinue use of the affected item codes and lots listed.
2. Please complete the attached Updated 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**

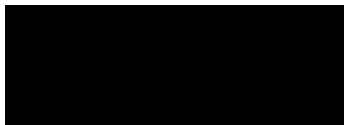
Please complete the Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology Recalled Return Form (attached) and contact your Distributor directly. All affected product and Recalled Product Return Form must be returned through the Distributor.

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
Quality Management System Manager
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

Attachment B

Item code



REF CA15L2

Emprint™

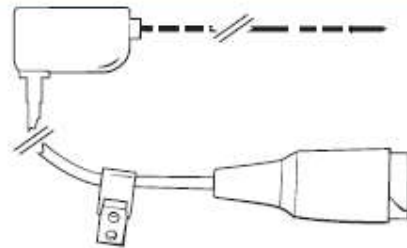
Short Percutaneous Antenna with Thermosphere™ Technology

Large Spherical Ablation Zone - Reinforced Antenna
15 cm

Antenne percutanée courte avec technologie Thermosphere

Large zone d'ablation sphérique - antenne renforcée

Antena percutánea curta con tecnología Thermosphere
Zona de ablación esférica de grande porte - antena reforzada
Kurze perkutane Antenne mit Thermosphere Technologie
Großer sphärischer Ablationsbereich - Verstärkte Antenne
Antena percutánea curta con tecnología Thermosphere
Zona grande de ablación esférica - Antena reforzada
Antenna percutanea curta con tecnologia Thermosphere
Zona di ablazione sferica ampia - Antenna rinforzata
Korte perkutane antenne met Thermosphere technologie
Grote sferische ablatiezone - Verstevigde antenne
Kort perkutan antenn med Thermosphere-teknologi
Stort sfærisk ablatjonsområde - Forstærkt antenn
Koponca sferična zona za ablacijo - forstærkt antenn
Большая сферическая зона абляции - усиленная антенна
采用 Thermosphere 技术的短径皮天线
大型球面消融区 - 增强天线
Kısa yarımküre antena s teknolojiya Thermosphere
Широка сферична зона за аблация - подсилена антена
Kratka perkutana antena s tehnologijom Thermosphere
Velika kulovita ablatna zona - zesiljena antena
Kort, perkutan antenne med Thermosphere-teknologi
Stort, kugleformet ablatjonsområde - forstærket antenne
Tehnoloogiat Thermosphere kasutab tihke perkutaanne antenni
Suur sfääriline ablatsoonitsoon - tugevatatud antenn
Thermosphere-teknilõõka sisaldava tihytk perkutaanne antenni
Suuri ympyrämuotoisen ablaatioalue - vahvistettu antenni
Kortri sfæriske ablatjonszone med Thermosphere
Μεγάλη σφαιρική ζώνη αποδόσης - Ενισχυμένη κεφαλή
Kratka perkutana antena za ruvođenje s Thermosphere tehnologijom
Velika sfera zona ablacije - pojačana antena
Thermosphere tehnologijaju rövü perkutan antena
Nagy, gömb alakú ablatós zóna - megerősített antenna
짧은 굵기 경우 안테나(Thermosphere 기술 적용)
커다란 구형 절제 영역 - 강화 안테나
Isa perkutana antena ar Thermosphere tehnologijju
Liela sfēriska ablaācijas zona - pastiprināta antena
Trumpa perkutane antena su Thermosphere tehnologijju
Dobrá sferická ablačná zóna - susedpřirná antena
Antenna Percutanea Curta b' Tecnologija Thermosphere
Zona ta-Asportazzjoni Sferika Kbira - Antenna Rinforzata
Kort perkutan antenne med Thermosphere-teknologi
Stort sfærisk ablatjonsområde - Forstærket antenne



Kratka elektroda prezeskorna w technologii Thermosphere
Duża sferyczna strefa ablacji - wzmacniona elektroda
Kratka perkutana antena s tehnologijom Thermosphere
Velika sfericka ablatna zona - zesiljena antena
Kratka antena za perkutano upotrebno s tehnologijom Thermosphere
Velika območje sferične ablacije - ojačana antena
Kratka perkutana antena sa Thermosphere tehnologijom
Velika sfera zona ablacije - pojačana antena
Antenă scurtă pentru intervenție percutanată cu tehnologie Thermosphere
Regione de ablazione sferica mare - antena rinforzata
Thermosphere Tehnologiji Kisa Perkutana Antena
Büyük Sferik Ablasyon Zona - Güçlendirilmiş Anten
採用 Thermosphere 技術之短徑下腔式天線
大型的半圓球狀消融區 - 強化天線



May be covered by U.S. Patents: www.covidien.com/patents
© 2016 Covidien. Made in China.
Manufactured for Covidien Inc, 15 Thermosphere Street, Mansfield, MA 02048 USA.
Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.
P7000-07880



Lot number printed here



49 Changi South Avenue 2
Singapore 486056
www.medtronic.com

tel +65 6436 5000
fax +65 6776 6355

UPDATED 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
Hospital / HCP/Distributor:	Name:
Address:	By Email:
	By Post:
Telephone no:	
Fax no:	
E-mail:	

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 acknowledge receipt of the UPDATED Covidien Emprint™ Percutaneous Antennas with Thermosphere™ Technology device recall notification dated 19 November 2018 and understand the recall instructions provided.

Name: _____ (print) Signature: _____ Stamp: _____ Date: _____

