

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.

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 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 directly 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 distributor	Complete all 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,

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™

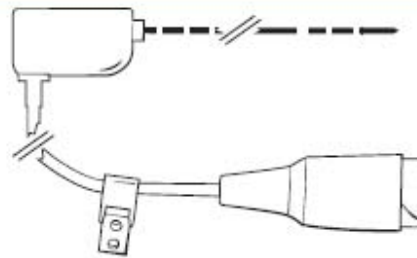
Short Percutaneous Antenna with Thermosphere™ Technology

Large Spherical Ablation Zone - Reinforced Antenna
15 cm

Antenne percutanée courte avec
technologie Thermosphere

Large zone d'ablation sphérique - antenne renforcée

Antena 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 - Versterkte antenne
Kort perkutan antenn med Thermosphere-teknologi
Stort sfäriskt ablationsområde - Förstärkt antenn
Короткая сферическая 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
Кьса поддрожна антена с технология Thermosphere
Широка сферична зона за аблация - поддрожна антена
Kratka perkutana antena s tehnologijom Thermosphere
Velika kulovita ablatna zona - zesilená antena
Kort, perkutan antenne med Thermosphere-teknologi
Stort, kugleformet ablationsområde - förstärkt antenne
Tehnoloogiat Thermosphere kasutav lühike perkutanne antenn
Suur sfääriline ablatsoonitsoon - tugevdatud antenn
Thermosphere -teknoloogias sisaldatud lühyl perkutaaniline antenni
Suuri ympyrämuotoinen ablaatioalue - vahvistettu antenni
Короткий радиочастотный керамический излучатель Thermosphere
Μεγάλη ημικυκλική ζώνη αποδόσης - Ενισχυμένη κεφαλή
Kratka perkutana antena za ravotanje s Thermosphere tehnologijom
Velika sferna zona ablacije - ojačana antena
Thermosphere tehnologijom rvid perkutan antena
Nagy, gömb alakú ablációs zóna - Megerősített antenna
짧은 파부 경우 안테나 (Thermosphere 기술 적용)
커다란 구형 절제 영역 - 강화 안테나
Isa perkutana antena ar Thermosphere tehnologijom
Liela sfēriska ablácijs zona - pastiprinata antena
Trumpa perkutanimé antena sa Thermosphere tehnologijom
Diólael sterinés ablácijs zona - sustiprinta antena
Antenna Percutanea Qasira b' teknoloija Thermosphere
Zona tal-Asportazzjoni Sferika Kbira - Antenna Rinforzata
Kort perkutan antenne med Thermosphere-teknologi
Stort steriskt ablationsområde - Förstärkt antenne



Kratka elektroda przezskłona w technologii Thermosphere
Duża sferyczna strefa ablacji - wzmacniona elektroda
Kratka perkutana antena s tehnologijom Thermosphere
Velika sfēriska ablatna zona - zesilená antena
Kratka antena za perkutano uporabo s tehnologijom Thermosphere
Veliko območje sterilne ablacije - ojačana antena
Kratka perkutana antena sa Thermosphere tehnologijom
Velika sferna zona ablacije - ojačana antena
Antena scurtă pentru intervenție percutanată cu tehnologie Thermosphere
Regiune de ablație sferică mare - antenă ramforată
Thermosphere Tehnologiji Kisa Perkutan Anten
Büyük Sferik Ablasyon Zonu - Güçlendirilmiş Anten
採用 Thermosphere 技術之短经皮下式天線
大型的半圓球狀消融區 - 強化天線



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Lot number printed here