Medtronic

60 Middletown Avenue
North Haven, CT 06473
USA
www.medtronic.com

MEDICAL DEVICE CORRECTION
Covidien Emprint™ Ablation Pumps, Remote Temperature Probes, Reusable Cables and Generators

April XX, 2019

Attention: Risk Management Director and O.R. Materials Management

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is issuing a field correction for specific item codes of Covidien Emprint™ devices distributed in China. This voluntary action is being conducted to align the intended use statements listed in the Instructions for Use (IFU) brochures with the China license registration. There are no patient safety implications or quality issues related to this action. You may continue to use your Emprint™ devices. This voluntary action affects the IFUs distributed with the item codes listed below.

Item Code	Description
CAPUMP1	Emprint™ Ablation Pump
RTP20	Remote Temperature Probe for use with Emprint™ Ablation System
CA190RC1	Emprint™ Ablation Reusable Cable
CAGEN1	Emprint™ Ablation Generator

The revised Instructions for Use (IFU) brochures list the intended use for the above devices which are consistent with the NMPA license for these devices. A printed copy of the revised IFU will be forwarded to you by May 31, 2019. The revised language in the IFU is:

> *Intended use: The product is intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of liver tumors, not intended for use in cardiac procedures. Note: The individual single lesion of target tumor should not be more than 5 cm in diameter; for multiple lesions, the number of lesions should not be more than 3 and each the average size of lesion should not be greater than 3 cm.*

Please share this revised IFU information with all users of Emprint™ devices in your facility. If you have distributed the Emprint™ devices listed above, please promptly forward the information from this letter to those recipients. Please dispose of all IFUs that are currently at your facility following receipt of the revised documents.

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This action is being taken with the knowledge of NMPA. We request that you contact Medtronic if you experienced quality problems or adverse events.

- Email Medtronic Post Market Vigilance at: cqa@medtronic.com

Required Actions:

1. Upon receipt of the revised IFUs, please dispose of IFUs included with the products listed in the table above.
2. Notify all users of Covidien Emprint™ devices of the revised IFU information.
3. Please complete the reply form even if you have no inventory of the affected product listed above.

We sincerely apologize for any inconvenience this situation may cause you or your facility. Thank you for your attention to this notification.

Sincerely,

China RA
Medtronic

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Medical Device Correction Notice
Acknowledgement and Receipt Form—Response is Required
Covidien Emprint™ Ablation Pumps, Remote Temperature Probes, Reusable Cables and Generators

Please complete this form in its entirety.

Date: _____

Name of Person Completing this form: _____

Title: _____

Direct Phone#: _____

Email: _____

Account Name: _____

Account Number: _____

Account Address: _____

City: _____ State: _____ Zip Code: _____

Telephone Number: _____

I have read and understand the instructions provided and acknowledge receipt of the Medical Device Correction Notice regarding Covidien Emprint™ ablation pumps, remote temperature probes, reusable cables and generators by signing below. I also agree to further distribute and communicate this important information within my facility and to any facility that I have further distributed Covidien Emprint™ ablation pumps, remote temperature probes, reusable cables and generators as required.

Product purchased through distributor: Contact to your Distributor directly.

_____ _____ _____

Name (print) Signature (Signature Required)
Date

PLEASE EMAIL OR FAX THIS ACKNOWLEDGMENT TO:
Medtronic: XXX@medtronic.com

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医疗器械现场纠正行动通知函

微波消融系统

2019 年 4 月 4 日

尊敬的客户：

本公司正在对销往中国的特定产品型号和批次的微波消融系统发起现场纠正行动。此现场纠正行动的目的是更正产品说明书中的“适用范围”描述，使其与产品注册证一致。此次行动与患者安全或产品质量问题无关，您可继续使用该微波消融系统产品（注册证号：国械注进20173255063）。

本次纠正行动依据《医疗器械召回管理办法》（国家食品药品监督管理总局令第29号）第三条的相关内容发起并执行。

本次纠正行动涉及以下型号批号产品的说明书：

型号	批号			
CA190RC1	EC17071087	EC17191150	EC17191166	EC17221195
	EC17071088	EC17191151	EC17221173	EC17221201
	EC17071089	EC17191160	EC17221177	EC17301226
	EC17071096	EC17191163	EC17221188	EC17301243
	EC17301245			
CAGEN1	EG17050611	EG17050618	EG17090636	EG17110662
	EG17050614	EG17080634	EG17090641	EG17130702
	EG17050616	EG17080635	EG17090660	EG17130703
	EG17170731	EG17170735		
CAPUMP1	455000	552619	552639	555515
	517113	552622	555513	555523
	517115	552637	555514	592707
	517117	552638		
RTP20	71070164X			

新说明书完成备案后，关于适用范围的描述更正为如下文字，以与相应产品注册证一致：

适用范围：“产品适用于肝肿瘤的经皮、腔镜和术中的凝固（消融），但不可用于心脏手术。注意事项：单个肿瘤病灶应不大于5cm；多发病灶应不多于3个且每个不大于3cm。”

我司将为您提供备案后的新说明书，以替换您目前库存中以及在用产品的旧版说明书。

COVIDIEN HEALTHCARE INTERNATIONAL TRADING (SHANGHAI) CO., LTD.

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请将此更正后的说明书信息告知贵单位的所有受影响的用户，如果您已将以上所列产品配送到他处，请立即将此函中的信息转给产品接收方。在收到我司提供的新版说明书后，请将您当前的所有旧版说明书销毁。

请严格按照修正后的产品说明书使用相关产品，关注使用过程中的潜在风险，如果在使用中出现任何异常，请暂停使用，并立即寻求我司的协助，若出现任何可能的疑似不良事件，向您所在地的省级食品药品监督管理部门和卫生行政管理部门报告。

本次行动已上报相应监管机构，如有质量问题或者不良事件，烦请联系我司。

应采取的行动：

1. 收到更正后的新版说明书后，请将以上列表产品中的旧版说明书销毁。
2. 通知微波消融系统所有的使用者及产品接收方关于更正说明书的信息。
3. 烦请完整填写附件《确认函》（即使您已没有以上所列产品的库存）。

对于这次行动给您及您单位造成的不便，我们深表歉意。感谢您对该通知的关注。

此致

敬礼

柯惠医疗器材国际贸易（上海）有限公司

2019 年 4 月 4 日