

MEDICAL DEVICE RECALL

Emprint™ Ablation System

July XX, 2019

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

Dear Valued Distributor:

The purpose of this letter is to advise you that Medtronic is issuing a voluntary recall at the direction of NMPA's Shanghai Enforcement Team, under the Administration of Market Surveillance Agency, MSA, for Emprint™ ablation systems in China only. This recall is being conducted because not all devices included in the approved license were distributed to customers.

There are no patient safety implications or quality issues related to this action. The impacted item codes and serial numbers of Emprint™ systems in-scope of the recall are listed in the table below.

Item Code	Description	Serial Number
CAGEN1	Emprint™ Ablation Generator	
CA190RC1	ABLATION REUSABLE CABLE X1	
CAPUMP1	ABLATION PUMP X1	
RFASW	RF ABLATION FOOTSWITCH EX1	
RTP20	REMOTE TEMPERATURE PROBEX1	

Required Actions:

1. Please immediately quarantine the affected serial numbers listed above.
2. If you have distributed the Emprint™ ablation systems listed above, please promptly forward the information from this letter to those recipients.
3. Sign the "Quarantine Commitment Agreement".
4. Complete the Acknowledgement Form **even if you do not have inventory**.

	Customer with inventory	Customer with zero inventory	Where to send the completed 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"	Fax to xxx-xxx-xxxx or email XXXXXXG@Medtronic.com

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

Sincerely,

Subu Mangipudi
Vice President, Quality Assurance
Respiratory, Gastrointestinal & Informatics
Medtronic

ACKNOWLEDGEMENT FORM

Response is Required

Covidien Emprint™ Ablation System

Customers must complete the form even if you do not have inventory.

Date:

Name of Person Completing this Form: Title:

Direct Phone #: Email

Distributor:

Account Name:

Account #:

Account Address:

City:

State: Zip Code:

RETURN INVENTORY TO: Medtronic, Attn: Field Returns Dept. 195 McDermott Road North Haven, CT 06473 USA

Return Goods Authorization (RGA) #: _____ (please include once received from Customer Service)

No Inventory (Please check): ☐

Item Code	Serial Number	Quantity

I acknowledge receipt of the Emprint™ ablation system recall notification dated July XX, 2019 and understand the recall instructions provided.

(Signature Required)

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO:

Product purchased through distributor: GMBFCAMITG@Medtronic.com or fax it to (203) 492-7719.