

URGENT MEDICAL DEVICE RECALL

February 15, 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 voluntarily recalling a specific production lot of its

Covidien Force TriVerse™ electrosurgical device 10' cord.

Issue Description:

This voluntary recall is being conducted due to the potential for the sterile packaging to be compromised. The use of products with this condition may result in a potentially increased risk for infection. There have been no reports of infection associated with this issue.

This voluntary recall affects only the item code and lot listed below.

Item Code	Description	Lot Number
FT3000	Force TriVerse™ Electrosurgical Device	80390309X

Medtronic requests that you quarantine and return any unused products of the item code and production lot detailed above. Unused products from the affected item code should be returned as described in the Required Actions section below. If you have distributed Force TriVerse™ electrosurgical devices 10' cord listed above, please promptly forward the information from this letter to those recipients. All unused products from the affected item code and lot must be returned.

Required Actions:

1. Please immediately quarantine and discontinue use of the affected item code and lot listed above.
2. Please return affected product as indicated below.
3. If you have distributed Force TriVerse™ electrosurgical devices 10' cords listed above, 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	Complete the Recalled Product Return Form and fax to: 800-895-6140 Ship affected product with RGA# provided by Customer Service to: Medtronic Attn: Field Returns 195 McDermott Road North Haven, CT 06473 USA	Complete form and check the box indicating "no inventory"	Fax to 800-895-6140 or email feedback.customerservice@covidien.com Exception: Customers with zero inventory, fax to 203-492-7719 or email to FCAMITG@Medtronic.com
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 203-492-7719 or email FCAMITG@Medtronic.com

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

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

The FDA can be contacted to report any adverse events experienced with the use of these products:

- Online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (form available to fax or mail), or Call FDA 1-800-332-1088

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative or Customer Service at 800-962-9888, option 2.

Sincerely,



J. Bryan Dannettell
Vice President, Quality Assurance
Surgical Innovations
Minimally Invasive Therapies Group
Medtronic

Attachment A



Item code

Lot number

RECALLED PRODUCT RETURN FORM Covidien Force TriVerse™ Electrosurgical Device 10' Cord PLEASE COMPLETE THIS FORM

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

Date:
Name of Person Completing this Form: Title:
Direct Phone #: Email:

How did the account purchase this product? (Please complete **ONLY** A or B)

Direct from Medtronic (Complete A): **From a Distributor (Complete B):**

A. Direct Customers:

Account Name:
Account #:
Account Address:

City:
State: Zip Code:

B. From a Distributor:

Distributor:
Customer Information:
Customer Name:
Address:
City:
State: Zip:

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	Lot Number	Qty	Case or Each

I acknowledge receipt of the Covidien Force TriVerse™ electrosurgical device 10' cord device recall notification dated February 15, 2019, and understand the recall instructions provided.

(Signature Required)

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO:

Product purchased directly from Medtronic: feedback.customerservice@Covidien.com or fax to (800) 895-6140.

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