



March 16, 2017

### RE: Product recall – Covidien Curity Eye Pad

The purpose of this letter is to provide information regarding a *voluntary* recall issued by Medtronic Canada. This voluntary recall is being conducted due to the potential for the sterile packaging to be compromised on specific item codes and production lots of the Covidien Curity Eye Pad.

F.A.S.T. Limited has received this voluntary recall as an active holder of a **Medical Device Establishment License (MDEL)**. The **MDEL** provides Health Canada the assurance that we have met the regulatory requirements and have documented procedures in place, where applicable, related to distribution records, complaint handling, storage, and delivery.

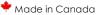
Our records indicate your organization has purchased one or more of the following first aid kits manufactured and assembled by F.A.S.T. between January 1, 2013 and March 14, 2017 which may contain the recalled Curity Eye Pad.

F.A.S.T. Code	Product Description
EKIT1030	Survival First Aid Kit
EKIT1030RPL	Survival First Aid – Replacement
EKIT1100	Survival First Aid Jump Kit
EKIT1220	Classroom Pack First Aid Kit
EKIT1230	Classroom Pack First Aid w/EKIT1220
EKIT1435T	Principal Pack w/ First Aid
MKIT1050	First Aid Kit – TransMountain Pipeline
MKIT1056.1	First Aid Kit – Sea Land Aviation
MKIT1180	Life Boat First Aid Kit
MKIT1190	Life Raft First Aid Kit
MKIT1323	Finning – BC/AB OHS 2
MKIT1516	Alberta OHS 2

The safety and peace of mind of our customers is of utmost importance to us. We appreciate your assistance.

Sincerely, F.A.S.T. First Aid & Survival Technologies Limited

Carmen Ewles General Manager 604-940-3222 | <u>cewles@fastlimited.com</u>







### **Recall Procedure**

Please follow instructions below if you wish to have the Curity Eye Pad in the above kits replaced:

- 1. Immediately quarantine any product with the catalogue numbers and lot.
- 2. After product consolidation, please fill out the Product Recall form attached, and fax it to 604-940-3221 or email it to <u>cewles@fastlimited.com</u>.
- 3. Ship product back to F.A.S.T. Limited warehouse (8850 River Rd., Delta BC, V4G 1B5) with the Product Recall form enclosed with the shipment.
- 4. Once returned product has been received at our warehouse, replacement quantities will be sent to the company address indicated on the Product Recall form.
- 5. Please respond, if possible, by *March 31, 2017*.

# Medtronic

#### Medtronic Canada

Patient Monitoring & Recovery 8455 Trans-Canada Highway Saint-Laurent, Quebec H4S 1Z1 medtronic.ca

877-664-8926

### URGENT MEDICAL DEVICE RECALL

Covidien Curity Eye Pad™

#### Attachment A Distinguish affected product by Item Code and Lot Number: Front of package: Item code Front LOT Back COVIDIEN" **REF** 91650 Curity<sup>™</sup> LOT 16F073962 OT 16 F073962 101 2021.06 8 Eye Pad 2021-06 8 8 **Compresse pour les yeux** Almohadilla para ojos Compressa ocular STERILE Single Do not use if package is opened or damaged **EXPIRY** © 2011 Covidien. Made in USA. Covidien IIc, 15 Hampshire Street, Mansfield, MA 02048 USA. AG62958734

### MEDICALMART

MEDICAL MART. 6200 Cantay Road Mississauga, Ontario L5R 3Y9

March, 2017

#### MEDICAL DEVICE RECALL URGENT PRODUCT RECALL

### \*\*\*Please respond by March 31, 2017\*\*\*

It has become necessary to recall the following product(s):

**Product Name and Catalogue Number:** 

Item Code	Item Description	Lot Number beginning with	Expiration Date
91650	Covidien Curity Eye Pad	12, 13, 14, 15, 16	From 2017-02 through 2021-11

### Reason: (Manufacturer's Recall)

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific item codes and production lots of the Curity Eye Pad, Curity Wet Dressing, Kerlix Super Sponge Saline Dressing, Curity Sodium Chloride Dressing and Curity Saline Dressing.

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.

Medtronic requests that you quarantine and return any unused products of the items/ lots detailed below. Unused products from the affected item codes and lots should be returned as described in the Required Actions section below.

Form 05B Form Issue Date: Jul. 07, 2014



## **Product Recall Form**

ITEM CODE	ITEM DESCRIPTION	LOT NUMBER beginning with	EXPIRY DATE
91650	Covidien Curity Eye Pad	12, 13, 14, 15, 16	From 2017-02 through to 2021-11

We HAVE the following affected products and have discontinued use and distribution. We have quarantined the affected products and will be retuning the following quanitities.

Product Code		LOT#		Quantity (in EACHES)
91650	_		_	
91650	_		_	
91650	_		_	
91650	_		_	
91650	_		_	

Please use the address required for replacements delivery.

Company:		
Address:		
City/Prov:		
Contact:		
Tel #:		
Email:		
Fax #:		
Signature:	Date:	Please enclose this form with return shipment after
		faxing to <b>604-940-3221</b> or emailing to <b>cewles@</b> <b>fastlimited.com</b>