

## **UPDATED URGENT FIELD SAFETY NOTICE** **Valleylab™ Laparoscopic Handset, Four-Function**

May 1, 2017

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

Dear Valued Customer:

The purpose of this letter is to advise you of an update to our February XX, 2017, communication related to Medtronic's Field Safety Corrective Action (FSCA) for specific production lots of its Covidien Valleylab™ laparoscopic handset, four-function (Item Code: E2750). This update is related to additional lots being added to the FSCA. The additional lots are listed below.

This FSCA is being conducted following customer reports of the Valleylab™ laparoscopic handset continuing to operate after release of the activation button. If the device continues to operate after deactivation by the user, it can increase the potential for internal tissue burn/damage. There have been no reports of serious injury associated with this FSCA.

Medtronic requests that you quarantine and return any unused products of the lots detailed below. Unused products from the affected lots should be returned as described in the Required Actions section below. If you have distributed the Valleylab™ laparoscopic handset listed below, please promptly forward the information from this letter to those recipients. All unused products from the affected lots must be returned.

Item	Description	Affected Lots			
E2750	Valleylab™ Laparoscopic Handset Four- Function	62160366X	62640134X	62900103X	63180106X
		62160368X	62770129X	62900107X	63500104X
		62580134X	62780258X	62970174X	63280159X
		62670122X	62740115X	63360172X	63470097X

This action is being taken with the knowledge of the Saudi Food and Drug Authority. We request that you contact Medtronic if you experienced quality problems or adverse events.

- Email Medtronic Regulatory Affairs at: [ksa.ra@medtronic.com](mailto:ksa.ra@medtronic.com)

## Required Actions:

1. Please quarantine and discontinue use of the affected item code and lots listed above.
2. Please return affected product as follows:

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased <b>directly</b> 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 <b>distributor</b>	Complete <b>all</b> 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.

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative at [amr.abdel.azim@medtronic.com](mailto:amr.abdel.azim@medtronic.com)

Sincerely,



J. Bryan Dannettell  
Vice President, Quality Assurance  
Surgical Innovations  
Medtronic

Attachment A

Distinguish affected product by Item Code and Lot Number.



Valleylab™

Laparoscopic Handset

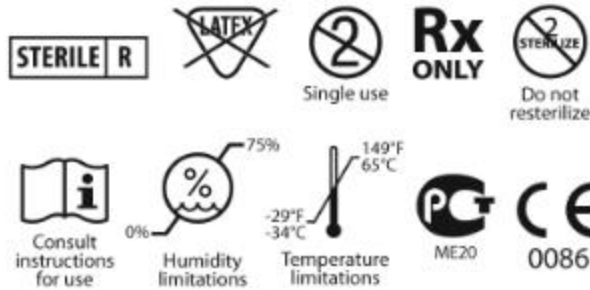
Four-Function

Instrument à main coelioscopique

Quadri-fonction

REF E2750 ← Item #

LOT ← Lot #



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