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**URGENT MEDICAL DEVICE RECALL**  
**Valleylab™ Laparoscopic Handset, Four-Function**

6 February 2017

**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 specific item codes and production lots of its Covidien Valleylab™ laparoscopic handset, four-function. This voluntary recall 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 recall.

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. 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 item codes and lots must be returned. This voluntary recall affects only the item codes and lots listed on listed below.

Item	Description	Affected Lots				
E2750	Valleylab™ Laparoscopic Handset Four-Function	52990142X	53250061X	53610059X	60240065X	61220095X
		52990144X	53250063X	53610061X	60520098X	61220098X
		52990147X	53250065X	60240055X	60520104X	61300164X
		52990151X	53610053X	60240059X	60870064X	61540145X
		53250057X	53610055X	60240061X	61220093X	61540150X

**Required Actions:**

1. Please quarantine and discontinue use of the affected item codes and lots listed.
2. Please complete the attached Recalled Product Return Form in its entirety. If you do not have any units from the affected lots in your inventory, simply tick "No affected inventory to be returned" and revert back to your local Medtronic Representative.
3. Please return affected product as follows:

- **CUSTOMERS WHO PURCHASED PRODUCT DIRECTLY FROM MEDTRONIC**

Please complete the Valleylab™ Laparoscopic Handset, Four-Function Recalled Return Form (attached) and return to your local Medtronic representative together with affected units if any.

- **CUSTOMERS WHO PURCHASED PRODUCT FROM A DISTRIBUTOR**

Please complete the Valleylab™ Laparoscopic Handset, Four-Function Recalled Return Form (attached) and contact your Distributor directly. All affected product and Recalled Product Return Form must be returned through the Distributor.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required. We request that you contact Medtronic if you experienced quality problems or adverse events.

If you have any questions or concerns regarding this recall, please do not hesitate to contact your local Medtronic representative.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused.

Sincerely,



Diana Teo  
QA Supervisor  
Medtronic

Attachment A

Distinguish affected product by Item Code and Lot Number.

 **COVIDIEN**  
*positive results for life™*  
**Valleylab™**  
**Laparoscopic Handset**  
Four-Function  
**Instrument à main coelioscopique**  
Quadri-fonction

**REF E2750**

← **Item #**

**LOT**

← **Lot #**



**STERILE R**



Single use

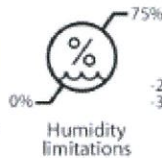
**Rx  
ONLY**



Do not  
resterilize



Consult  
instructions  
for use



Humidity  
limitations



Temperature  
limitations




ME20



0086

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■ Covidien Inc, 15 Hampshire Street, Mansfield, MA 02048 USA.

 Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.  
1070317



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**RECALLED PRODUCT RETURN FORM**  
**Valleylab™ Laparoscopic Handset, Four-Function**

**ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY**

Customer Contact Details	Medtronic Contact Details
Hospital / HCP:	By E-mail:
Address:	By Post:
Telephone no:	
Fax no:	
E-mail:	

Please tick (either one) only:

☐ No, no affected inventory to be returned.

☐ Yes, affected inventory to be returned (Please fill up the below table if chosen)

Item code	Product Description	Lot number	QTY (Each)

I have read and understand the instructions provided and acknowledge receipt of the Recall regarding Covidien Valleylab™ Laparoscopic Handset recall dated 6 February 2017 by signing below:

Name: \_\_\_\_\_ (print) Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Even if you have no affected stock, please complete this form and return to your local Medtronic contacts stated above**