



49 Changi South Avenue 2
Singapore 486056
www.medtronic.com

tel 65.6482.0100
fax 65.6482.0300

URGENT MEDICAL DEVICE RECALL
Covidien Valleylab™ Laparoscopic Electrodes

11th July, 2016

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

Please forward this communication to all surgeons, surgical personnel and any other potential users of the product.

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific item codes and production lots of Covidien Valleylab™ Laparoscopic Electrodes. This voluntary recall is being conducted due to the potential for compromise of the package resulting in a breach of the sterile barrier. The use of products with this packaging defect may increase risk of infection. There have been no reports of serious injury associated with this issue.

Medtronic requests that you quarantine and return any unused products of the items/lots detailed on **Attachment A**. 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 sterile Valleylab™ Laparoscopic Electrode products listed on **Attachment A**, 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 **Attachment A**.

Attachment A: Affected Item Codes and Lot List

Item Code	Material Description	Affected Lot Range
E253028	Valleylab™ Laparoscopic Flexible Laparoscopic Argon Electrodes	210141X through 61220104X
E25303	Valleylab™ Laparoscopic Flexible Laparoscopic Argon Electrodes 3"	210286X through 61220102X
E25306	Valleylab™ Laparoscopic Flexible Laparoscopic Argon Electrodes 6"	209154X through 60870078X
E258028	Valleylab™ Laparoscopic Flexible Laparoscopic Argon Blade Electrodes 28CM	210573X through 60870080X
E258128	Valleylab™ Laparoscopic Argon Modified Flat I Electrode 28CM	211742X through 60870082X
E258228	Valleylab™ Laparoscopic Argon Sharp Needle Electrode 28CM	216416X through 60080002X
E258328	Valleylab™ Laparoscopic AP Argon Blunt Needle Electrode 28cm	210556X through 60520063X
E277036	Valleylab™ Laparoscopic Straight Spatula Electrode 36C	215084X through 61220127X
E277136	Valleylab™ Laparoscopic Curved Spatula Electrode 36CM	210654X through 61380120X
E277145	Valleylab™ Laparoscopic Curved Spatula Electrode 45CM	209505X through 61220130X
E277236	Valleylab™ Laparoscopic Wire J-Hook Electrode 36CM	210110X through 61250197X
E277336	Valleylab™ Laparoscopic Wire J-Hook Electrode 36CM	00378X through 61220135X

E277436	Valleylab™ Laparoscopic Flat L-Hook Electrode 36CM	210652X through 61390114X
E278028	Valleylab™ Laparoscopic Straight Spatula Electrode 28CM	212060X through 60520072X
E278128	Valleylab™ Laparoscopic Curved Spatula Electrode 28CM	209716X through 61220115X
E2781R28ASP	Valleylab™ Laparoscopic Curved Spatula Electrode Retractable 28CM	209358X through 60870083X
E278228	Valleylab™ Laparoscopic Wire J-Hook Electrode 28CM	209822X through 61220117X
E2782R28ASP	Valleylab™ Laparoscopic Wire J-Hook Electrode Retractable	213559X through 60520066X
E278328	Valleylab™ Laparoscopic Wire L-Hook Electrode 28CM	209965X through 60870090X
E2783R28ASP	Valleylab™ Laparoscopic Wire L-Hook Electrode Retractable	209284X through 60870084X
E2783R36ASP	Valleylab™ Laparoscopic Wire L-Hook Electrode Retractable	208908X through 61220113X
E278428	Valleylab™ Laparoscopic Flat L-Hook Electrode 28cm	209220X through 52140033X
E2784R28ASP	Valleylab™ Laparoscopic Flat L-Hook Electrode Retractable	209503X through 60870086X
E278628	Valleylab™ Laparoscopic Cylindrical Tip Electrode 28CM	213786X through 61220121X
E277345	Valleylab™ Laparoscopic Wire J-Hook Electrode 45CM	210409X through 61220133X

Required Actions:

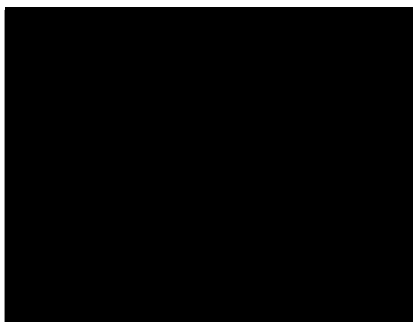
1. Please quarantine and discontinue use of the affected item codes and lots listed on **Attachment A**.
2. Please complete the attached Product Return Form in its entirety. If you do not have any units from the affected lots in your inventory, simply tick **“No affected inventory to be returned”** and revert back to your local Medtronic Representative.
3. Please return affected product as follows:
 - **CUSTOMERS WHO PURCHASED PRODUCT DIRECTLY FROM MEDTRONIC**
Please complete the Laparoscopic Electrode Product 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 Laparoscopic Electrode Product Return Form (attached) and contact your Distributor directly. All affected product and Recalled Product Return Form must be returned through the Distributor.

This action has been notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required.

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,



Attachment B

Distinguish affected product by Item Code and Lot Number.

COVIDIEN™
Valleylab™
Laparoscopic Argon Blunt Needle Electrode
Retractable
28 cm

REF E2583-28

ITEM CODE

LOT NUMBER

Laparoscopic Argon Blunt Needle Electrode, Retractable
Électrode à aiguille non tranchante argon coelioscopique, rétractable
Laparoskopische stumpfe Argon-Nadelelektrode, einziehbar
Electrodo laparoscópico de aguja roma de argón, retráctil
Electrodo smussato ad ago ad argon laparoscópico, retrabile
Electrodo com agulha roma laparoscópico de argônio, retrátil
Laparoskopisk trubbig argonålektrodelektrod, inådragbar
Laparoskopische stompe Argon-naaldelektrode, inåttkbar
Лапароскопический аргонеский тупой игольчатый электрод, выдвигной
腹腔镜用(钝针)电极、可收短

STERILE EO
SATEX
Single use
Rx ONLY
Do not use if package is opened or damaged
Consult instructions for use
HOPE
M229
CE 0085
Do not use if package is opened or damaged
Consult instructions for use
HOPE
M229
CE 0085
Live by

© 2011 Covidien. Made in USA.
Covidien UK, 15 Hampshire Street, Mansfield, MA 02048 USA.
Covidien Ireland Limited, IDM Business & Technology Park, Tullamore, 1043773.

(01)10884524000923

Medtronic

49 Changi South Avenue 2
Singapore 486056
www.medtronic.com

tel 65.6482.0100
fax 65.6482.0300

RECALLED PRODUCT RETURN FORM

Covidien Valleylab Laparoscopic Electrodes

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 Electrode Device 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