

URGENT FIELD SAFETY NOTICE

Covidien Valleylab™ Laparoscopic Electrodes

July 18, 2016

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

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is recalling specific item codes and production lots of Covidien Valleylab™ Laparoscopic Electrodes. This Field Safety Corrective Action (FSCA) 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 FSCA affects only the item codes and lots listed on Attachment A.

This action is being taken with the knowledge of the Irish Competent Authority, The Health Products Regulatory Authority (HPRA). If you become aware of any incidents related to this issue, please contact your local Medtronic Representative using the contact information detailed in this notice to provide information regarding those events so regulatory reporting obligations can be fulfilled.

Required Actions:

1. Please quarantine and discontinue use of the affected item codes and lots listed on Attachment A.
2. Please return affected product as follows:

	Customer with inventory:	Customer with Zero Inventory	Where to send the completed form
Purchased DIRECTLY from Medtronic	<p>Please complete the attached Returns Verification Form in its entirety and e-mail it to audrey.doyle@medtronic.com or fax to 01 439 3039</p> <p>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.</p>	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 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".	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 Sales Manager Enda Mulvany by telephone 87 6152267 or by e-mail at enda.mulvany@medtronic.com.

Sincerely,



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



Audrey Doyle
 RA Specialist,
 Email: audrey.doyle@medtronic.com

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
E277345	Valleylab™ Laparoscopic Wire J-Hook Electrode 45CM	210409X through 61220133X
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

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

Laparoscopic Argon Blunt Needle Electrode, Retractable
Electrode 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
Laparoskopiisk trubbig argon-nadelelektrodelektrod, indragbar
Laparoskopische stumpfe Argon-nadelelektrode, einziehbar
Лaparоскопический аргоневый тупой игловый электрод, выдвигаемый
腹腔镜氩气钝针电板，可收能

STERILE EO **SAFE** **2** **Rx ONLY** **Do not reuse**
Do not use if package is opened or damaged **Consult instructions for use** **HDPE** **MS21** **0086**

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(01)10884524000923

LOT

LOT NUMBER