Medtronic
60 Middletown Avenue
North Haven, CT 06473
USA
www.medtronic.com

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

February XX, 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 recalling specific production lots of its Covidien Valleylab™ laparoscopic handset, four-function (Item Code: E2750). This Field Safety Corrective Action (FSCA) is being conducted following customer r ports of the Valleylab™ laparoscopic handset continuing to operate after release of the activation button. If the device continues to operate after deactivatio 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 retur 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 yo have distributed the Valleylab™ laparoscopic handset listed below, please promptly forward the infor ation from this letter to those recipients. All unused products from the affected lots must be returned. This FSCA affects only the item code and lots 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

This action is being taken with the knowledge of the [Insert name of local Competent Authority]. We request that you contact Medtronic if you experienced quality problems or adverse events.

- Email Medtronic Regulatory Affairs at: XXXXX@Medtronic.com

Required Actions:
1. Please quarantine and discontinue use of the affected item code and lots listed above.

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2. Please return affected product as follows:

	Customer with inventory	Customer with ze o inventory	Where to send he comple edform
Purchased **directly** from Medtronic	Please complete the attached Returns Verification Form i its entiret . 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 “noinventory”	E-mail or fax the completed form to the Medtro ic 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 “noinventory”	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 a y questions or concerns, please do not hesitate to contact your Medtronic representative at (XXX) XXX-XXXX.

Sincerely,

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Medtronic

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Attachment A

Distinguish affected product by It m Code and Lot Number.