Medtronic

Minimally Invasive Therapies Group
60 Middletown Avenue
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USA
www.medtronic.com

URGENT FIELD SAFETY NOTICE

Beacon™ EUS delivery system needles

February X, 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 item codes and production lots of Covidien Beacon™ EUS Delivery System needles. This Field Safety Corrective Action (FSCA) is being conducted following customer reports that the handle of the Beacon™ EUS Delivery System separated during use due to a manufacturing error. Use of a device with a separated handle can increase the potential for user needle sticks. Needles sticks have been associated with transmission of HBV, HCV, and HIV to healthcare personnel. There was one report of a user needle stick associated with this FSCA.

Medtronic is requesting that you quarantine any remaining inventory of the item codes and lot numbers 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 Covidien Beacon™ EUS Delivery System devices affected by this FSCA to other persons or facilities, please promptly forward the information from this letter to those recipients. All affected units must be returned.

This FSCA affects only the item codes listed below.

Item Code	Product Description	Lot Number
DSC-22-01	Covidien SharkCore™ Fine Needle Biopsy System (22 GA)	B000000164, B000000170, B000000173, B000000178
DSN-19-01	Covidien BNX™ Fine Needle Aspiration System (19GA).	B000000176, B000000181
DSC-25-01	Covidien SharkCore™ Fine Needle Biopsy System (25 GA)	B000000174
DSL-19-01	Covidien SharkCore™ LG Fine Needle Biopsy System (19 GA)	B000000166
DSN-22-01	Covidien BNX™ Fine Needle Aspiration System (22GA)	B000000167

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Required Actions:

1. Please quarantine and discontinue use of the affected item codes 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 **directly** 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 **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.

This action is being taken with the knowledge of the [Insert name of local Competent Authority]. We request you report any quality problems experienced with the use of this product to Medtronic:

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

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative at (XXX) XXX-XXXX.

Sincerely,

Jim Thomas

Timothy Thomas
Vice President, Regulatory Affairs and Quality Assurance
Early Technologies
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Attachment A

Distinguish affected product by Item Code and Lot Number