Medtronic

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URGENT MEDICAL DEVICE RECALL
Clearify™ Visualization System

04 October 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 voluntarily recalling specific item codes and production lots of our Clearify™ visualization system.

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.

We request that you quarantine and return any unused products of the items/lots detailed below. Unused products from the affected lots should be returned as described in the "Required Actions" section below. If you have distributed the sterile Clearify™ visualization system products listed below, please promptly forward this letter to those recipients. All unused products from the affected lots must be returned.

This voluntary recall affects only the item codes and lots listed below:

Item Code	Product	Affected Lot Prefixes and Lots
21-345	Clearify™ Visualization System	Lots beginning with: P4J, P4K, P4L, P4M, P5A, P5B, P5C, P5D, P5E, P5F, P5G, P5H, P5J, P5K, P5L, P5M, P6A, P6B, P6C, P6D and lots P6E0016GX, P6D0049GX, P6E0050GX, P6E0051GX, P6E0052GX, P6E0163GX, P6E0164GX, P6E0212GX

Required Actions:

1. Please quarantine and discontinue use of the affected item codes and lots listed on Attachment A.

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 Clearify™ Visualization System 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 Clearify™ Visualization System 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.

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,

[redacted]

Senior QA Operations Specialist
Medtronic

Attachment A

Distinguish affected product by Item Code and Lot Number

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RECALLED PRODUCT RETURN FORM
Clearify™ Visualization System

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Covidien 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 the Clearify Visualization System 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