



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

tel 65.6482.0100
fax 65.6482.0300

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**

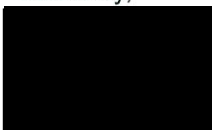
Please complete the Clearify™ Visualization System Recalled Return Form (attached) and contact your Distributor directly. All affected product and Recalled Product Return Form must be returned through the Distributor.

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,



Senior QA Operations Specialist
Medtronic

Attachment A

Distinguish affected product by Item Code and Lot Number

Item Code

↓



COVIDIEN
positive results for life®

Clearify™

Visualization System

REF

21-345

Lot Number

XXXXXX

LOT

XXXXXXXXXX

Use by XXXX-XX-XX



Visualization System with Warming Hub, Microfiber Cloth and Trocar Wipe

Système de visualisation avec embase de chauffage, tissu à microfibres et essuie-trocar

Visualisierungssystem mit Aufwärmknoten, Mikrofaser Tuch und Trokar Wischtuch

Sistema di visualizzazione con attacco termico, panno in microfibra e tampone di pulizia trocar

Sistema de visualización con botón de calentamiento, paño de microfibra y trocar de limpieza

Sistema de Visualização com Centro de Aquecimento, Pano de Microfibras e Limpador de Trocar

Visualisatiesysteem met verwarmingselement, microvezeldoek en trocartissue

Visualiseringssystem med uppvärmningsstation, mikrofiberduk och trokartorkare

Visualiseringssystem med opvarmningsplade, mikrofiberklud og vådserviet til trokar

Puhdistusjärjestelmä, johon kuuluu lämmitin, mikrokuituliina ja trokkaaripuhkko

Σύστημα οπτικής απεικόνισης με θέρμανση θερμαντήρα, πανί από μικροβέλος και παντήλα καθαρισμού τροκάρ

System do wizualizacji z bazą podgrzewającą, ściereczką z mikrofibry i sztytem do wyderania trokara

Istma Göbekli, Mikrofiber Bezli ve Trokar Temizleyicili Görüntüleme Sistemi

Система визуализации с блоком подогрева, микрофибровыми салфетками и зондом для чистки троакара

Vizualizační systém s ohřevacím rozbočovačem, látkou z mikrovlákna a trokarovým tamponem

Képalátó rendszer melegítőegységgel, mikroszálas törölkendővel és trokártörölővel

STERILE R

This product does not contain natural rubber latex

Rx ONLY

Do not resterilize

Do not use if package is opened or damaged

Caution, consult accompanying documents

© 2014 Covidien. Made in USA.

Covidien LLC, 15 Hampshire Street, Mansfield, MA 02048 USA.

Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.

1080464



0123



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

tel 65.6482.0100
fax 65.6482.0300

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