

URGENT FIELD SAFETY NOTICE

Clarify™ Visualization System

October 11, 2016

Attention: Risk Management Director and OR Materials Management

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is recalling specific production lots of item code 21-345, Clarify™ Visualization System.

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 the 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 item/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 Clarify™ Visualization System products listed below, please promptly forward 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 Code	Product	Affected Lot Prefixes and Lots
21-345	Clarify™ 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, P6E0049GX, P6E0050GX, P6E0051GX, P6E0052GX, P6E0163GX, P6E0164GX, P6E0212GX

This action is being taken with the knowledge of the Irish Competent Authority, The Health Products Regulatory Authority (HPRA). We request that you contact us if you experienced quality problems or adverse events.

- Email Medtronic Regulatory Affairs at: audrey.doyle@medtronic.com

Required Actions:

1. Please quarantine and discontinue use of the affected 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 affected 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 representative.

Sincerely,



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



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

Attachment A

Distinguish affected product by Item Code and Lot Number

Item Code

COVIDIEN
positive results for life®

Clearify™
Visualization System

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, Mikrofasertuch und Trocarwischtuch
 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, Paño de Microfibra e Limpador de Trocar
 Visualisatiesysteem met verwarmingselement, microvezeldoeken trocartissue
 Visualiseringssystem med uppvärmningsstation, mikrofiberduk och trocartorkare

REF 21-345

LOT XXXXXXXXXX
 Use by XXXX-XX-XX

Lot Number

STERILE R

This product does not contain natural rubber latex

Single use

Rx ONLY

Do not resterilize

Do not use if package is opened or damaged

Caution, consult accompanying documents

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