

4500 Parkway
Whiteley
Hampshire
PO15 7NY
www.medtronic.com

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE
Cytosponge™ Cell Collection Device

June 16, 2016

[Redacted]

Dear [Redacted]

The purpose of this letter is to advise you that Medtronic is recalling all item codes and production lots of Covidien Cytosponge™ Cell Collection Device. This Field Safety Corrective Action (FSCA) is being conducted following customer reports of the Cytosponge™ device detaching from the retrieval string during withdrawal from the patient’s esophagus. When the sponge detaches from the string, retrieval of the sponge is achieved through endoscopy. There have been no reports of serious patient injury associated with this recall.

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 Cytosponge™ Cell Collection Device 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 all item codes. Listed below are the lots that are within the expiration period.

Item Code	Description	Lot#
CYTO-KIT-R	Covidien Cytosponge™ Kit – R	3441120915
CYTO-KIT-R	Covidien Cytosponge™ Kit – R	3441102015
CYTO-101-01	Covidien Cytosponge™ Device	F2500566X
CYTO-101-01	Covidien Cytosponge™ Device	F2500628X
CYTO-101-01	Covidien Cytosponge™ Device	F2500202X
CYTO-101-01	Covidien Cytosponge™ Device	F2500351X

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 and e-mail it to amanda.woolven@medtronic.com or fax to 01329 224418. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products.	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

This action is being taken with the knowledge of the local Competent Authority and other regulatory authorities. We request you report any events and/quality problems experienced with the use of this product to the Competent Authority and Medtronic:

- MHRA Phone: [+44 20 3080 6000](tel:+442030806000), E-mail : AIC@mhra.gsi.gov.uk
- Medtronic Representative Fax: 01329 224418 E-mail: amanda.woolven@medtronic.com

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative.

Sincerely,

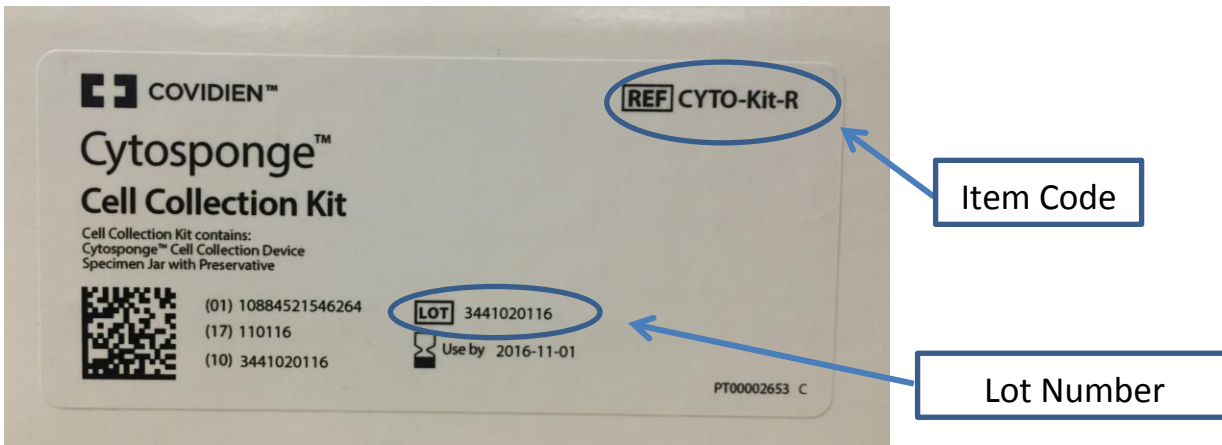


Amanda Woolven
Regulatory Affairs
Amanda.woolven@medtronic.com
Tel. 01329 224435

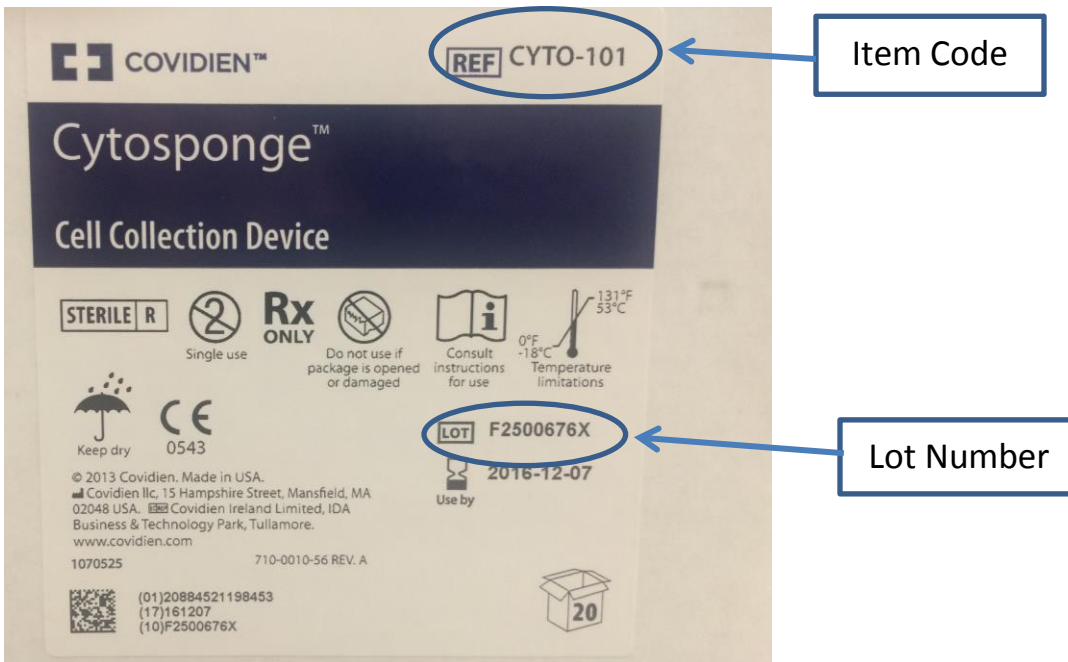
Attachment A

Distinguish affected product by Item Code and Lot Number.

Cyto Kit-R



Cyto-101-01-box



through distributor: Quality Compliance MITGFCA@Covidien.com or fax it to (203) 492-7719.

URGENT MEDICAL DEVICE Field Safety Corrective Action

Cytosponge™ Cell Collection Device

VERIFICATION FORM PLEASE COMPLETE THIS FORM IN ITS ENTIRETY

[Please insert date the form was sent]

Customer Contact Details	Medtronic Contact Details
Hospital Name: Covidien/Medtronic Account Number:	To: [please insert name]
Collection Address: Department: Street: City: Postal Code: Contact Person at Point of Collection: Opening Hours:	Address: [please insert Medtronic address]
Telephone:	Telephone: [please insert Medtronic telephone number]
Fax:	Fax: [please insert Medtronic fax number]
E-mail:	E-mail: [please insert contact e-mail address]

Item Codes: Refer to attachment A of the Urgent Field Safety Notice.

Please list the quantity of affected product at your facility, if you have **no** inventory, please tick the box below.

No Inventory (Please check):

Item Code	Invoice or Despatch Note (if available)	Lot number	Quantity (Eaches or Boxes) Please specify

- **Please complete this form and return it to Medtronic even if you have no affected inventory**

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Information for the courier:

Number of parcels to collect: _____

Weight: < 45kg > 45kg

By signing this form I confirm that I have read and understand the Urgent Field Safety Notice from Medtronic regarding all lots of the Cytosponge™ Cell Collection Device issued dated June, 2016

<u>Customer Name: (Please Print)</u>	<u>Signature:</u>	<u>Date:</u>

- Please fax or email this form back to Medtronic within 10 days using the contact details referenced at the top of this form.
- Customer Service will contact you directly to organise return of affected products.
- Please don't send the goods back before having received the return documentation.
- **This action is being taken with the knowledge of the [add local Competent Authority].**