

URGENT FIELD SAFETY NOTICE

Shiley™ Neonatal, Pediatric and Long Pediatric Tracheostomy Tube, Cuffless Shiley™ Neonatal, Pediatric and Long Pediatric Tracheostomy Tube with TaperGuard™ Cuff

Product Recall

May 15, 2015

FSCA Ref: Shiley 05/15

Attention: Risk Management Director and O.R. Materials Management

Please forward this communication to all surgeons, surgical personnel, and any other potential users of the product.

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is recalling its Covidien Shiley™ Neonatal, Pediatric and Long Pediatric Tracheostomy Tube, Cuffless and Shiley™ Neonatal, Pediatric and Long Pediatric Tracheostomy Tube with TaperGuard™ Cuff due to an issue identified from customer complaints.

Medtronic is conducting this Field Safety Corrective Action (FSCA) following reports from customers where patients who recently switched from the current Shiley™ Neonatal and Pediatric products to the affected products experienced discomfort immediately after the switch in a limited number of situations. In some cases, breathing difficulties, corresponding to a negative effect on oxygen levels, were also observed immediately after the switch. In all reported cases, patients were administered immediate medical attention. **Serious injuries, events that required medical intervention, have occurred or could occur due to the failure mode associated with this FSCA. We have twelve (12) reports of serious injuries. No deaths have been reported.** The complaint rate for these reported complications is 0.06%.

If one of the recalled Shiley™ tracheostomy tubes is currently in use in a patient, and the patient is not experiencing any discomfort, breathing difficulties or any other issues related to the tube, we recommend that the patient's physician evaluate the continued use. If the physician advises leaving the tracheostomy tube in place, we encourage that the tube be replaced at the next interval.

Please review your inventory and segregate any product with the affected product codes and lot numbers shown in Attachment A. To easily identify affected product, please see Attachment B. Unused products from the affected product codes and lots should be returned as described in the Required Actions Section below.

REQUIRED ACTIONS:

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

2. Please return affected product as follows:

COMMERCIAL LTD	BLOCK G, GROUND FLOOR	+353 1 4381600 [T]
	CHERRYWOOD BUSINESS PARK	
	LOUGHLINSTOWN	
	DUBLIN 18	
	IRELAND	

• **CUSTOMERS WHO PURCHASED PRODUCT DIRECTLY FROM MEDTRONIC**

Please complete the Shiley™ Tracheostomy Tube Returns Verification Form and fax it to 01 439 3039 for the attention of Audrey Doyle or e-mail it to audrey.doyle@medtronic.com. If you do not have any units to return, simply return the form indicating you have zero (0) units.

Upon receiving your form, Customer Service will contact you to organize the return of your products. You will receive credit for unused and unexpired device(s) that you return. Please contact your local Representative Edel O'Sullivan by telephone 087 0620475 or by e-mail at Edel.OSullivan@hc21.ie for details on alternative product options.

• **CUSTOMERS WHO PURCHASED PRODUCT FROM A DISTRIBUTOR**

Please complete the Returns Verification Form (attached) and contact your Distributor directly for direction on returning product. The completed form should be emailed to the following address: audrey.doyle@medtronic.com or faxed to 01 439 3039. All affected product must be returned through the Distributor with a copy of the completed form.

• **ALL CUSTOMERS**

We ask that all customers reply to Medtronic **WHETHER OR NOT** you have affected product at your site. Your response is vital to our monitoring of the effectiveness of this recall. Please complete the Returns Verification Form Return form and return to Medtronic via the instructions provided.

Thank you for your business and continued support. This action is being taken with the knowledge of the Irish Competent Authority, The Health Products Regulatory Authority (HPRA). If you have any questions or concerns, please do not hesitate to contact your Medtronic representative.

If you are aware of any incidents related to this issue, please contact your local Representative using the contact information stated above to provide information regarding those events so regulatory reporting obligations can be fulfilled.

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

Sincerely,


Audrey Doyle

RA Specialist, Email: audrey.doyle@covidien.com Tel: 01 4381609

Attachment A

The FSCA is limited to the product codes and associated lot numbers listed in the table below. If you are unable to determine the lot number of any of the product codes and size listed in the above table, then those products should be treated as if they are within the affected lot numbers and you should proceed as directed below.

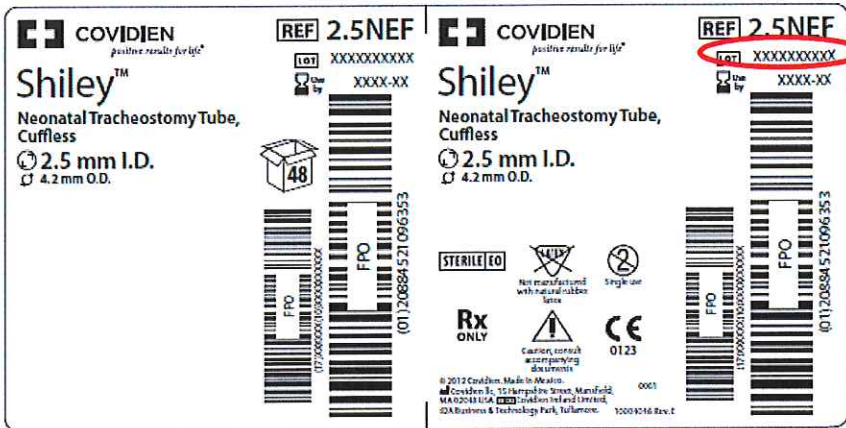
Cuffless products		
Product description name	Product Numbers	Lot
Neonatal Tracheostomy Tube Cuffless	2.5NEF	All lot numbers beginning with 12, 13 and 14
	3.0NEF	
	3.5NEF	
	4.0NEF	
	4.5NEF	
Pediatric Tracheostomy Tube Cuffless	2.5PEF	
	3.0PEF	
	3.5PEF	
	4.0PEF	
	4.5PEF	
	5.0PEF	
Pediatric Tracheostomy Tube Long Cuffless	5.5PEF	
	5.0PELF	
	5.5PELF	
	6.0PELF	
	6.5PELF	

Cuffed products

Product description name	Product Number	Lot
Neonatal Tracheostomy Tube with TaperGuard™ Cuff	2.5NCF	All lot numbers beginning with 12, 13 and 14
	3.0NCF	All lot numbers beginning with 12, 13 and 14; Lot number 15A0152JZX
	3.5NCF	All lot numbers beginning with 12, 13 and 14; Lot number 15A0154JZX
	4.0NCF	All lot numbers beginning with 12, 13 and 14
	4.5NCF	All lot numbers beginning with 12, 13 and 14; Lot number 15A0155JZX
Pediatric Tracheostomy Tube with TaperGuard™ Cuff	2.5PCF	All lot numbers beginning with 12, 13 and 14; Lot number 15A0153JZX
	3.0PCF	All lot numbers beginning with 12, 13 and 14, Lot number 15A0151JZX
	3.5PCF	All lot numbers beginning with 12, 13 and 14
	4.0PCF	
	4.5PCF	
	5.0PCF	
5.5PCF		
Pediatric Tracheostomy Tube Long with TaperGuard™ Cuff	5.0PLCF	All lot numbers beginning with 12, 13 and 14
	5.5PLCF	
	6.0PLCF	
	6.5PLCF	

Attachment B

Distinguish affected product by Lot number on the Shipper, Carton Labels



COVIDIEN positive results for life®
Shiley™
 Neonatal Tracheostomy Tube, Cuffless
 2.5 mm I.D.
 4.2 mm O.D.

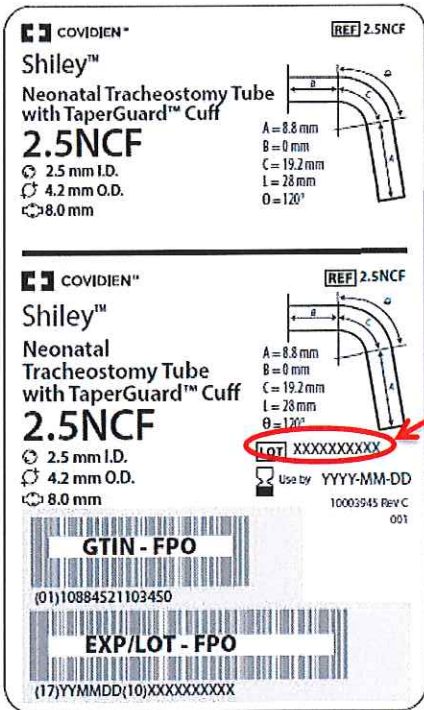
REF 2.5NEF
 Lot XXXXXXXXXXXX
 Use by XXXX-XX

COVIDIEN positive results for life®
Shiley™
 Neonatal Tracheostomy Tube, Cuffless
 2.5 mm I.D.
 4.2 mm O.D.

REF 2.5NEF
 Lot XXXXXXXXXXXX
 Use by XXXX-XX

STERILE EO
 Not manufactured with natural rubber latex
 Single use
 Rx ONLY
 Caution, consult accompanying documents
 CE 0123
 © 2012 Covidien. Made in Mexico.
 Covidien Inc., 75 Karpagba Street, Mansfield, MA 02125 USA
 Covidien Ireland Limited, IDA Business & Technology Park, Tullamore, 1000 X016 Rev.1

Lot Number



COVIDIEN
Shiley™
 Neonatal Tracheostomy Tube with TaperGuard™ Cuff
2.5NCF
 2.5 mm I.D.
 4.2 mm O.D.
 8.0 mm

REF 2.5NCF
 A = 8.8 mm
 B = 0 mm
 C = 19.2 mm
 L = 28 mm
 θ = 120°

COVIDIEN
Shiley™
 Neonatal Tracheostomy Tube with TaperGuard™ Cuff
2.5NCF
 2.5 mm I.D.
 4.2 mm O.D.
 8.0 mm

REF 2.5NCF
 A = 8.8 mm
 B = 0 mm
 C = 19.2 mm
 L = 28 mm
 θ = 120°
 Lot XXXXXXXXXXXX
 Use by YYYY-MM-DD
 10009945 Rev C
 001

GTIN - FPO
 (01)10884521103450

EXP/LOT - FPO
 (17)YYMMDD(10)XXXXXXXXXX