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 XX, 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:

• CUSTOMERS WHO PURCHASED PRODUCT DIRECTLY FROM MEDTRONIC

Please complete the Shiley™ Tracheostomy Tube Returns Verification Form and fax it to xxx-xxxxx for the attention of [Insert Local RA contacts name].or email it to INSERT LOCAL EMAIL ADDRESS. If you do not have any units to return, simply return the form indicting 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 Covidien representative 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: LOCAL CONTACT EMAIL ADDRESS or faxed to (XXX)-XXX-XXXX. 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 (INSERT LOCAL REGULATORY AUTHORITY NAME). 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 Medtronic 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,

Lisa Newcombe-Dierl
Vice President Manufacturing Quality, Patient Monitoring & Recovery
Medtronic

Or local signature

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	
	5.5PEF	
Pediatric Tracheostomy Tube Long Cuffless	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	
	5.5PLCF	
	6.0PLCF	
	6.5PLCF	

Attachment B

Distinguish affected product by Lot number on the Shipper, Carton Labels and Product Tray Labels.