COVIDIEN

URGENT MEDICAL DEVICE RECALL

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

11 May 2015

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 Covidien (a Medtronic company) is voluntarily recalling its 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.

Covidien is conducting this voluntary recall 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 recall. 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.

COVIDIEN PRIVATE LIMITED
CO. REGISTRATION NO: 199800515M

103 PENANG ROAD
VISIONCREST COMMERCIAL
#10-01
SINGAPORE 238467

65-6482-0100[T]
65-6482-0300 [F]

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REQUIRED ACTIONS:

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

2. Immediately advise all users of this Recall. Please complete the attached Recalled product Return Form in it's entirely. If you do not have any units from the affected lots in your inventory, simply return the recall form indicating you have zero(0) unit and return the completed form to your local Covidien office.

3. Please return affected product as follows:

   a. Customers who purchased product directly from Covidien , please complete the Recalled Product Return Form and our local Covidien representative will arrange the pick-up.

   b. If you purchased product from a distributor please complete the Recalled Product Return Form and contact your Distributor directly. The completed form and all affected units 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 Covidien representative.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused.

Yours sincerely,

[redacted]

Alec Chow
Director, Post Market Vigilance, Asia
Covidien

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Attachment A

The recall 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	

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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	

Disposable Bedside Tray (Tray contains 4 units)		
Product description name	**Product Number**	**Lot**
Neonatal Tracheostomy Tube Cuffless, Disposable Bedside Tray	3.0NEF-P	All lot numbers beginning with 12, 13 and 14
	3.5NEF-P	
	4.0NEF-P	
	4.5NEF-P	
Pediatric Tracheostomy Tube Cuffless, Disposable Bedside Tray	3.0PEF-P	
	3.5PEF-P	
	4.0PEF-P	
	4.5PEF-P	
	5.0PEF-P	
	5.5PEF-P	

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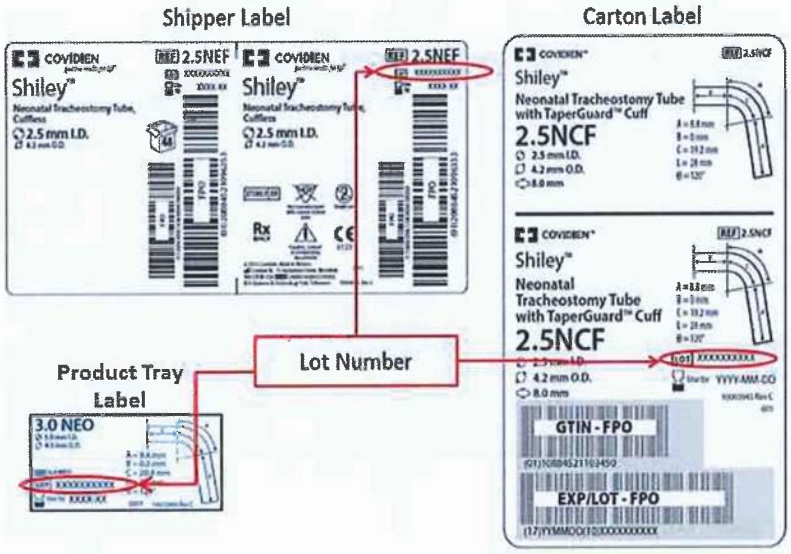
Attachment B

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



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Recalled Product Return Form

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

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	Expiry Date	QTY (Each)

I have read and understand the instructions provided and acknowledge receipt of the Recall regarding Palindrome Catheter by signing below

Name: _____ (Print) Signature: _____ Date: _____

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