U.S. Food and Drug Administration
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Recall -- Firm Press Release

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Medtronic Implements Worldwide Voluntary Recall for Certain Lots of Neonatal and Pediatric Tracheostomy Tubes

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FOR IMMEDIATE RELEASE – June 23, 2015 – Dublin, Ireland – Medtronic (NYSE: MDT) announced that on May 8, 2015, it began notifying hospitals and distributors worldwide that affected lots of its Covidien Shiley(TM) tracheostomy tubes were formed with a wider-angle bend than standard models manufactured after November 29, 2012.

The company initiated the field action following a small number of customer complaints that included reports of 12 serious patient injuries, such as breathing difficulties that impacted oxygen levels immediately upon tube placement or discomfort. Replacement of the tracheostomy tube with product manufactured prior to November 29, 2012 addressed the patient breathing difficulty or discomfort. The notification requested all customers and distributors to quarantine and discontinue use of all potentially affected units and return the affected product to the company as soon as possible for credit.

Customers and distributors, who have provided the recalled Shiley tracheostomy tubes to a homecare provider or patient, must notify the primary care physician and the homecare provider that these products should be discontinued from use and returned. If one of the recalled products is currently in use in a homecare patient, and the patient is not experiencing any discomfort, breathing difficulties or any other issues related to the tube, it is recommended

that the patient's physician evaluate the continued use. If the physician advises leaving the tracheostomy tube in place, the tube must be replaced with an alternate device at the next tube exchange.

Medtronic also took the necessary steps to prevent future shipments of the recalled products. The company also notified regulatory agencies around the world, as appropriate. Since November 29, 2012, Shiley tracheostomy tubes were shipped into Australia, Belgium, Canada, Chile, Germany, Israel, Italy, Japan, Saudi Arabia, Singapore, South Africa, Turkey, Uruguay and the United States of America.

A Shiley tracheostomy tube is put through a patient's trachea (windpipe) during a tracheostomy procedure to help provide an airway and facilitate the ability to breathe.

The recall includes specific lots from the following eight product lines that were manufactured after November 29, 2012.

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 table, then those products should be treated as if they are within the affected lot numbers.

Lot numbers will appear on the product labeling and the number is structured with the first two digits representing the year of manufacturing, i.e., 12 is for 2012, 13 is for 2013 and 14 is for 2014.

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

Cuffed Products		
Product Description Name	Product Numbers	Lot

Cuffed Products		
Product Description Name	Product Numbers	Lot
Shiley Neonatal Tracheostomy Tube with TaperGuard(TM) Cuff	2.5NCF	All lot numbers beginning with 12, 13 and 14
	3.0NCF	All lot numbers beginning with 12, 13 and 14; and Lot number 15A0152JZX
	3.5NCF	All lot numbers beginning with 12, 13 and 14; and 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; and Lot number 15A0155JZX
Shiley Pediatric Tracheostomy Tube with TaperGuard(TM) Cuff	2.5PCF	All lot numbers beginning with 12, 13 and 14; and Lot number 15A0153JZX
	3.0PCF	All lot numbers beginning with 12,13 and 14; and Lot number 15A0151JZX
	3.5PCF 4.0PCF 4.5PCF 5.0PCF 5.5PCF	All lot numbers beginning with 12, 13 and 14
Shiley Pediatric Tracheostomy Tube Long with TaperGuard(TM) Cuff	5.0PLCF 5.5PLCF 6.0PLCF 6.5PLCF	All lot numbers beginning with 12, 13 and 14

Disposable Bedside Tray (Tray contains 4 units)		
Product Description Name	Product Numbers	Lot
Shiley Neonatal Tracheostomy Tube Cuffless, Disposable Bedside Tray	3.0NEF-P 3.5NEF-P 4.0NEF-P 4.5NEF-P	All lot numbers beginning with 12, 13 and 14
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	All lot numbers beginning with 12, 13 and 14

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/MedWatch/report.htm)**
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

or

- Email Medtronic Post Market Vigilance at: **HQTSWEB@COVIDIEN.COM (mailto:HQTSWEB@COVIDIEN.COM)** Call Medtronic Post Market Vigilance at: 800-635-5267 option 1, option 1, and again option 1. The call center hours of operation are 6:00am - 4:00pm Pacific time, Monday - Friday. Customers have an option to leave a message after hours.

About Medtronic
Medtronic plc (http://www.medtronic.com), headquartered in Dublin, Ireland, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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More in Recalls, Market Withdrawals, & Safety Alerts (/Safety/Recalls/default.htm)

PHOTO - Dale and Thomas Popcorn Issues Voluntary Recall of Certain Popcorn Products page 2 (/Safety/Recalls/ucm322061.htm)

PHOTO - Doctor's Best Issues Voluntary Nationwide Recall of Red Yeast Rice due to Undeclared Lovastatin (/Safety/Recalls/ucm402587.htm)

PHOTO - Jump Your Bones, Inc. Recalls Roo Bites (Cubes) Pet Treats (/Safety/Recalls/ucm428673.htm)

PHOTO - See's Candies, Inc. Issues Allergy Alert On Undeclared Milk In Dark Chocolate Blueberries (/Safety/Recalls/ucm365579.htm)

PHOTO - Sun Rich Fresh Foods Inc. Recalls Apple Slices Because Of Possible Health Risk (/Safety/Recalls/ucm445392.htm)

PHOTO - Teva Parenteral Medicines Initiates Voluntary Nationwide Recall of Select Lots of Adrucil® (fluorouracil Injection, Usp) 5 G/100 Ml (50 Mg/ml) Due to Particulate Matter