Class I Medical Device Recall: Certain Covidien Shiley Adult Tracheostomy Tubes

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: July 18, 2012

Product: Certain lots of Shiley size 8 adult, reusable, cuffed tracheostomy tubes are included in this product recall. All other sizes and styles of Shiley tracheostomy tubes are unaffected by this action.

Model Numbers: Model numbers are provided on the FDA website [1].

Range of Manufacturing and Distribution Dates: Affected tracheostomy tubes were manufactured and distributed from October 1, 2009, to June 26, 2012.

Intended Use: A tracheostomy tube is a prescription device used by the order of a physician. It is placed through the patient's windpipe (trachea) during a surgical procedure called a tracheostomy to create an airway and provide a pathway to remove fluid from the trachea and lungs.

Inflatable cuff tracheostomy tubes have a soft balloon around one end of the tube that is inflated to seal off the space between the wall of the trachea and the tracheostomy tube during mechanical ventilation. The cuff prevents air from the ventilator from leaking around the tracheostomy tube and prevents injury to delicate tissue in the trachea.

Recalling Firm:
Nellcor Puritan Bennett Inc. (doing business as Covidien LP)
6135 Gunbarrel Avenue
Boulder, Colorado 80301-3214

Reason for Recall:
Covidien is recalling certain cuffed Shiley tracheostomy tubes due to consumer complaints related to reports of volume leakage and/or disconnection between the inner and outer cannulae, which were observed during mechanical ventilation of patients.

Public Contact: Customers with questions about this recall may contact Covidien Technical Services at (800) 635-5267, select option 3, and then option 1. Support is available during business hours with emergency service support available after these times.

FDA District: Denver

FDA Comments: Covidien notified customers of this recall by mail and phone and provided the following instructions:

- Customers should return all Shiley tracheostomy tubes from the affected models and lots to Covidien.
- If one of the recalled tubes is already in use in a patient, Covidien recommends that the tube be replaced as soon as clinically appropriate as determined by the patient's physician.
- If the physician advises leaving the tracheostomy tube in place, Covidien strongly encourages that the frequency of direct patient observation be increased.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm [2]. This web page also includes contact information to report by mail, by telephone, or by FAX.

Additional Information:

- Covidien Press Release [1]
- Photos of Shiley Product and Packaging [3]

Source URL (retrieved on *07/24/2014 - 5:14pm*):
http://www.mdtmag.com/news/2012/08/class-i-medical-device-recall-certain-covidien-shiley-adult-tracheostomy-tubes?qt-recent_content=0&qt-video_of_the_day=0

Links:
[1] http://www.fda.gov/Safety/Recalls/ucm314472.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
[3] http://www.fda.gov/Safety/Recalls/ucm314589.htm