Class I Medical Device Recall: Medtronic Xomed, Inc., NIM Trivantage EMG Endotracheal Tube

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: March 4, 2013

Product: NIM Trivantage EMG Endotracheal Tube

REF Numbers: 8229705, 8229706, 8229707, 8229708, 8229709, 8229735, 8229736, 8229737, 8229738, 8229739.

Lot Numbers: 205830052 to 206486732, 0206516104, 0206516105, 0206516106, 0206516108, 0206520224, 0206520225, 0206520226, 0206520227, 0206520228, 0206520358, 0206542163, 0206545356, 0206545502.

This product was manufactured from May 22, 2012 through Jan. 22, 2013 and distributed from July 27, 2012 through Feb. 14, 2013.

Use: The NIM Trivantage Endotracheal Tube is used by health care professionals to continuously monitor the voice box (laryngeal) muscles during surgery. The device keeps the patient’s airway open for ventilation and for electromyography (EMG) monitoring of the laryngeal muscles when connected to an appropriate EMG monitor.

Recalling Firm:
Medtronic Xomed, Inc.
6743 Southpoint Dr N
Jacksonville, Florida 32216-6218

Reason for Recall:
The firm received complaints of "cuff leak" or "cuff deflation" occurring when the inflation valve cap is inappropriately removed (pulled off, instead of snapped-off sideways). This requires the physician to re-inflate or replace the deflated tube to ensure the continued breathing support of the patient. Use of this recalled product can result in serious adverse health consequences, including death.

Public Contact: For questions about this recall, contact the firm’s Senior Regulatory Affairs Specialist at 1-800-874-5797.

FDA District: Florida District Office

FDA Comments:
On March 14, 2013, the firm sent an "URGENT Product Recall Notification" letter to

its customers. The letter described the product, problem, and actions to be taken.

Customers were instructed to return any affected devices still in their possession as follows:

- Check your inventories for the affected products listed on the enclosed checklist.
- Fill-in the "quantity on-hand" column on the checklist.
- Fax checklist to Medtronic ENT at 1-904-296-2386.
- Contact Medtronic ENT Customer Service at 1-800-874-5797 to arrange for returns, replacement, or credit.
- When returning products, clearly mark the outside of the container Returned Goods Authorization (RGA) number.
- If you have any questions regarding this recall or the content of the letter, contact the Senior Regulatory Affairs Specialist at 1-800-874-5797.

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 to MedWatch: The FDA Safety Information and Adverse Event Reporting Program [1] either online, by regular mail or by FAX.

Links:
[1] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm