FDA Public Health Notification: Complications from Metallic Tracheal Stents in Patients with Benign Airway Disorders

July 29, 2005

Dear Health care practitioner:

This is to alert you to serious complications associated with the use of metallic tracheal stents in patients with benign airway disorders, and to recommend specific actions to prevent or minimize the problem. This notification includes all covered and uncovered metallic tracheal stents.

Nature of the Problem

This notification focuses on patients with benign airway disorders because use of metallic stents in this patient population may preclude them from receiving future alternative therapies (such as tracheal surgical procedures or placement of silicone stents) after a metallic stent is removed. This patient population has a greater risk of serious complications than those with malignant disorders since the metallic tracheal stent is left in place longer.

Our concern about complications from using metallic tracheal stents in patients with benign airway disorders stems from a review of recently published literature, medical device reports that we have received, and information from physicians. These complications include obstructive granulation tissue, stenosis at the ends of the stent, migration of

the stent, mucous plugging, infection, and stent fracture. Although many of the medical device reports received by the FDA are associated with stent fracture, we believe that other complications cited in the literature are a potential risk with both covered and uncovered metallic tracheal stents.

Removal of metallic stents can also result in serious complications, including mucosal tears, severe bleeding, re-obstruction, respiratory failure with the need for postoperative mechanical ventilation, and tension pneumothorax. If the stent is removed in pieces due to device failure or fracture during removal, this can lead to unwanted permanent incorporation of retained stent fragments into tissue. Data evaluating the ability to safely and effectively remove embedded metallic stents from the trachea have never been provided to or reviewed by the FDA.

We recognize that metallic tracheal stents, when used appropriately on carefully selected patients, have benefit. We are currently working with manufacturers to ensure that the labeling of these stents adequately conveys the risks when they are used in patients with benign airway disorders.

Recommendations

- Use metallic tracheal stents in patients with benign airway disorders only after thoroughly exploring all other treatment options (such as tracheal surgical procedures or placement of silicone stents). Using metallic tracheal stents as a bridge to other therapies is not recommended, because removal of the metallic stent can result in serious complications.
- If a metallic tracheal stent is the only option for a patient, insertion should be done by a physician trained or experienced in metallic tracheal stent procedures.
- If removal is necessary, the procedure should be performed by a physician trained or experienced in removing metallic tracheal stents.
- Always review the labeling before using the device, especially the indications for use, warnings and precautions. Select patients carefully.

We urge you to be aware of the guidelines from professional organizations regarding recommended provider skills and competency for these procedures (i.e. training requirements and clinical experience). These guidelines include information about equipment, personnel, anesthesia and monitoring, techniques, indications, contraindication and risks.

Reporting Adverse Events to FDA

Prompt reporting of adverse events can improve FDA's understanding of and ability to communicate the risks associated with devices, and assist in the identification of potential future problems. The FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a

reportable adverse event was related to the use of a metallic tracheal stent, you should follow the reporting procedure established by your facility. When reporting the adverse event(s), you should specify whether the metallic tracheal stent was originally placed for a benign or malignant disorder.

We also encourage you to report adverse events related to metallic tracheal stents that do not meet the requirements for mandatory reporting. You can report these directly to the device manufacturer. You can also report to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online (https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm).

Getting More Information

FDA Medical Device Public Health Notifications (/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/default.htm) are available on the Internet. You can also be notified through email each time a new Public Health Notification is added to our web page. To subscribe, visit: http://service.govdelivery.com/service/subscribe.html?code=USFDA_39 (http://service.govdelivery.com/service/subscribe.html?code=USFDA_39).

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