Potential Risk of Airway Obstruction When Using Certain Electromyogram Endotracheal Tubes – Letter to Health Care Providers

April 27, 2022

The U.S. Food and Drug Administration (FDA) is evaluating the potential risk of airway obstruction when using silicone-based electromyogram (EMG) endotracheal tubes (Medtronic NIM Standard Reinforced EMG Endotracheal Tube and Medtronic NIM Contact Reinforced EMG Endotracheal Tube). The FDA has received reports describing serious adverse events and deaths for these devices after airway obstruction and ventilation failure. If the tube does not ventilate properly, patients may suffer oxygen deprivation, brain damage, or death.

At this time, the root cause and incidence rate of obstruction and ventilation failure with use of these devices is not known. However, information from medical device reports (MDRs) currently suggests that reported events of airway obstruction are more frequent for silicone-based EMG tubes compared to other tubes.

The FDA is encouraging you to report adverse events related to silicone-based EMG endotracheal tubes to the manufacturer and the FDA. Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. The FDA is working with the manufacturer to evaluate information from all available sources to provide additional information on this issue.

Recommendations

The FDA recommends that health care providers in the operating room setting, including anesthesiologists, nurse anesthetists, and surgeons:

- Be aware of the potential risk of airway obstruction and ventilation failure with silicone-based EMG endotracheal tubes.
- Follow the instructions for use in the device labeling to minimize the chance of ventilation failure and obstruction of the patient's airway.
- Be prepared to take immediate steps to reestablish a safe airway if ventilation failure occurs. Do not reintubate with a silicone-based EMG endotracheal tube.

- Report adverse events and outcomes to the FDA. Prompt reporting can help the FDA identify and better understand the risks associated with medical devices.

Background

EMG endotracheal tubes have electrodes for monitoring the integrity of nerves to the laryngeal musculature. These tubes are intended to provide an airway for patient ventilation and allow for intraoperative monitoring of EMG activity of the laryngeal musculature during surgery when connected to an appropriate EMG monitor. These devices are 510(k) cleared and are made from either polyvinyl chloride (PVC) or silicone elastomer. In the U.S., the currently marketed silicone-based EMG tubes are the Medtronic NIM Standard Reinforced EMG Endotracheal Tubes and Medtronic NIM Contact Reinforced EMG Endotracheal Tubes.

The FDA has received reports of serious adverse events and deaths after airway obstruction for silicone-based EMG endotracheal tubes. According to these reports, there is a risk of airway obstruction, ventilation failure, oxygen deprivation, and death. The root cause and incidence rate of these events is not known at this time. To date, the FDA has not received similar reports for EMG tubes made from PVC.

The FDA recognizes the limitations of MDR data, and reports submitted to the FDA are just one source the FDA uses to monitor and evaluate the safety and effectiveness of medical devices, in addition to published literature and other real-world data sources as they become available. The FDA will continue to evaluate all available information about the potential risk of airway obstruction with use of silicone-based EMG endotracheal tubes.

Following the instructions provided in the device labeling can reduce the risk of airway obstruction. Providers should be prepared to emergently manage airway obstruction and ventilation failure if it occurs during surgery by reestablishing a safe airway, and reintubate if needed with a new tube that is not a silicone-based EMG endotracheal tube. The FDA will continue to work with the manufacturer to ensure that health care providers are aware of the potential risk of airway obstruction and ventilation failure.

FDA Actions

The FDA is working with the manufacturer to further evaluate the issue and identify potential contributing factors and mitigation strategies. The FDA will inform the public if any significant, new information or recommendations become available.

Reporting Problems to the FDA

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with Medtronic NIM Standard Reinforced EMG Endotracheal Tubes and Medtronic NIM Contact Reinforced EMG Endotracheal Tubes. Prompt reporting can help the FDA identify and better understand the risks associated with medical devices and improve patient safety.

- Health care personnel employed by facilities that are subject to the FDA's User Facility Reporting Requirements (https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities#3) should follow the reporting procedures established by their facilities.
- Voluntary reports can be submitted through MedWatch: The FDA Safety Information and Adverse Event Reporting program (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations (https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).

Contact Information

If you have questions about this letter, contact the Division of Industry and Consumer Education (DICE) (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice).