Medical Xpress

Tracheostomy tubes recalled after 3 deaths

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(AP) -- A Massachusetts company is recalling tracheostomy tubes used to help patients on ventilators breathe after receiving reports that three people died while using them.

The company told the Food and Drug Administration that there were also about 1,200 complaints of leaks involving the recalled devices, said FDA spokesman Tom Gasparoli, adding the agency is investigating the deaths and complaints.

The recall affects tracheostomy tubes placed in patients' throats to help them breathe on ventilators.

Covidien, of Mansfield, Mass., said it was recalling certain cuffed Shiley-branded tracheostomy tubes and Shiley-branded custom tracheostomy tubes because the product's cuff may not hold air due to a possible leak in the pilot balloon.

The company said this could result in a sudden decrease in the amount of oxygen in the blood or a sudden increase in the amount of carbon dioxide. That can lead to serious injury or death.

Gasparoli said the FDA is "investigating the circumstances surrounding the deaths of three patients that may be associated with leaks in the tracheostomy tubes made by Covidien." Investigators will try to determine whether manufacturing problems led to the failures.

Covidien spokeswoman Sherri Hughes-Smith said the company received reports that a Shiley cuffed tracheostomy tube was in use when three patients died. "However, we have been unable to obtain detailed information about these incidents, so we cannot determine what role, if any, the product issue that led to this recall may have played," she said.

Adverse reactions can be reported to the Food and Drug Administration at 800-332-1088 or http://www.fda.gov/medwatch/report.htm .