carecentrix

Provider Newsflash
April 2023

FDA Recall – Covidien-Shiley Tracheostomy Tubes

Purpose of this communication:

- We are writing to inform you effective immediately, the FDA has issued notice of a Class 1 recall by Covidien of Shiley Adult Flexible Tracheostomy Tubes with TaperGuard Cuff and Cuffless with disposable Inner cannula or reusable inner cannula. A manufacturing error resulted in a less than specified diameter of the adult flexible tracheostomy tube connectors which results in unsecure connections with 15 mm caps and 15 mm circuit components and accessories. An unsecure connection could lead to respiratory failure, dyspnea, treatment delay, tissue injury or bleeding.

What do I need to do?

- Please review the following recall notice: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=199257
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.