

### FDA Recall – Medtronic

#### Purpose of this communication:

- We are writing to inform you that Medtronic and its subsidiary Covidien are recalling Shiley Adult Flexible Tracheostomy Tube with TaperGuard Cuff Reusable Inner Cannula because the tube may become dislodged or move out of place if the securement flange becomes disconnected. This could prevent the patient from breathing and/or block the airway, which may lead to a serious or life-threatening emergency. The use of a device that has disconnected the flange from the device cannula may result in respiratory failure, airway tissue injury, choking (aspiration), respiratory tract infection, tightening of the airways (bronchospasm), treatment delay and/or death. Medtronic has not reported any serious injuries or deaths related to this issue.

#### What do I need to do?

- Please review the following recall notice: [https://www.fda.gov/medical-devices/medical-device-recalls/flexible-tracheostomy-tube-recall-medtronic-removes-shiley-adult-flexible-tracheostomy-tube?utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/medical-devices/medical-device-recalls/flexible-tracheostomy-tube-recall-medtronic-removes-shiley-adult-flexible-tracheostomy-tube?utm_medium=email&utm_source=govdelivery)
- Notify impacted patients and facilitate the replacement, 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.