Provider Newsflash
October 2024

FDA Recall – Smiths Medical

Purpose of this communication:

- We are writing to inform you that Smiths Medical is recalling specific lots of the BLUSelect, BLUgriggs, and BLUperc products due to a manufacturing defect that may cause the pilot balloon to disconnect from the tracheostomy inflation line. If the pilot balloon used to inflate the tracheostomy cuff disconnects, pressure may not be maintained, which can lead to inadequate ventilation and increased risk of aspiration. The use of affected product may cause serious adverse health consequences, including aspiration and death. There have been 12 reported injuries. There have been no reports of death.
- Product Names:
    - BLUselect Tracheostomy Tube Kits
    - BLUselect Suctionaid Tracheostomy Tube Kits
    - BLUgriggs Percutaneous Dilation Tracheostomy Procedural Kit or Tray with BLUselect Tracheostomy Tube with or without Forceps
    - BLUperc Dilation Procedural Tray with Single Stage Dilator Products
    - BLUperc Percutaneous Dilation Tracheostomy Procedural Kit or Tray with or without BLUselect Tracheostomy Tube
        - Lot/Serial Numbers: See full list of affected products

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/medical-devices/medical-device-recalls/tracheostomy-tube-recall-smiths-medical-removes-bluselect-blugriggs-and-bluperc-tracheostomy-tube?utm_medium=email&utm_source=govdelivery
- Notify impacted patients and facilitate the replacement 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.

EDRC# 1604. 092021