PRODUCT DISRUPTION BRIEF

Tracheostomy tubes (updated July 29)

Medtronic recovery complete; ICU (Smiths Medical) is doubling safety stock.

Current conditions

Smiths Medical

On June 13, Smiths Medical issued an urgent medical device notification to notify providers of a potential defect with the specific BLUSelect®, BLUgriggs® and BLUperc® lots resulting in the potential disconnection of the pilot balloon from the tracheostomy inflation line. Affected product codes and lots are available here.

Required Actions:

When using the device, all instructions, including warning and cautions contained in the Instructions for Use documentation must be followed with heightened awareness. Please complete the following actions listed below:

- Check all inventory locations within your institution for the specific lots of the affected product codes listed in the notification and discontinue use. Discard all affected products following your institution's process for discarding. If discarding is not immediately possible at your facility, then the product should be quarantined until disposal.
- Share this notification with all potential users of the devices to ensure they are aware of this notification and proposed mitigations. If the devices are used at another location, please ensure this communication is delivered there.
- Contact your local representative with your certificate of destruction to coordinate the replacement/credit.

ICU Medical (Smiths Medical) is in good inventory position on all Tracheostomy products. They are now doubling their safety stock levels.

Medtronic

In Mar. 2023, Medtronic issued an urgent medical device recall for Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, and Cuffless: Disposable Inner Cannula or Reusable Inner Cannula due to reports that the device connector in some instances is not making a secure connection with the 15mm cap and other 15mm circuit components and accessories.

Medtronic is in a good state on Flex Disposable Adult tubes. However, still on backorder on some codes—see recovery information below:

- Flex Pediatric: 3.0PCF - recovered
- Flex Pediatric: 4.0NCF: recovered
- Fenestrated tubes: recovered
- Fenestrated Inner Cannulas: recovered

Mitigation strategy

The FDA recommends taking these steps to reduce the number of tracheostomy tubes used for each patient during the shortage:

- Follow the manufacturer's instructions for cleaning, sanitizing, and reusing tracheostomy tubes for the maximum number of times allowed.
- For example, Bivona tracheostomy tubes may be cleaned, sanitized, and reused as described in A Handbook for the Home Care of Your Child with a Tracheostomy for single-patient use, as stated in the indications for use, up to 5 times for pediatric sizes and 10 times for adult sizes.
- Work with your health care provider and durable medical equipment (DME) supplier to determine if appropriate alternatives, such as other FDA-cleared tracheostomy tubes that may use different raw materials, are available.

To learn more, please contact:
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- Recommendations for health care providers:
- Discuss these recommendations with patients who use the affected devices and their caregivers.
- Consider using these recommended conservation strategies in health care settings as well as encouraging their use in home settings.
- Contact your distributor or the manufacturer directly to inquire about current inventory, including if appropriate alternatives, such as other FDA-cleared tracheostomy tubes that may use different raw materials, are available.

Additional resources

Supply assurance webpage; Vizient Newsroom

Want to receive weekly Supply Assurance updates?
Update your preferences through our Subscription Manager by selecting Supply Assurance Weekly Digest.

Questions? Contact disasterresponse@vizientinc.com, pharmacyquestions@vizientinc.com, novaplus@vizientinc.com.