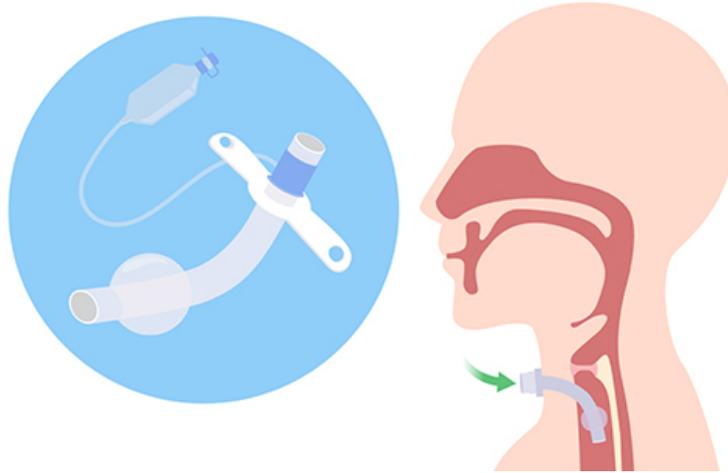


Tracheostomy Tube



Tracheostomy tube shortage likely to impact pediatric patients; FDA offers guidance

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With a shortage of tracheostomy tubes, the Food and Drug Administration is offering guidance to support health care providers and patients who need the equipment.

The shortage of tubes, including Bivona tracheostomy tubes manufactured by ICU Medical, is more likely to impact pediatric patients, the FDA said, because the supply of alternative tubes with similar functionality may be limited. Bivona tracheostomy tubes are made from flexible silicone material, which makes them easier to insert in pediatric patients to help them breathe.

The FDA [has released guidance](#) that caregivers and health care providers should consider until the shortage is resolved, which includes cleaning, sanitizing and reusing the tubes or switching to appropriate alternatives.

While other [tracheostomy tubes](#) have been cleared by the FDA for pediatric patients, there may not be enough available to mitigate the shortage.

The FDA is recommending several steps to reduce the number of tracheostomy tubes used for each patient during the shortage.

Recommendations for patients and caregivers include:

- 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 five times for pediatric sizes and 10 times for adult sizes.
- Work with your health care provider and durable medical equipment supplier to determine if appropriate alternatives, such as other [FDA-cleared tracheostomy tubes that may use different raw materials](#), are available.

Recommendations for health care providers include:

- Review the recommendations for patients and caregivers.

- 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.
- Ask your distributor or manufacturer about current inventory, including if appropriate alternatives are available.

ICU Medical has contacted customers to provide additional details on supply constraints and efforts to reduce the shortage.

If you are experiencing supply issues with tracheostomy tubes or other devices, [contact the FDA](#). Problems with a device should be reported using the [MedWatch Voluntary Reporting Form](#).

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