6000 Nathan Lane N
Minneapolis, MN 55442

URGENT MEDICAL DEVICE NOTIFICATION

Bivona® Aire-Cuf®, TTS™, Uncuffed, Mid-Range Neonatal/Pediatric Tracheostomy Tube(s) and Bivona Aire-Cuf®, TTS™, Cuffless FlexTend™, TTS™ FlexTend™ Adult Tracheostomy Tube(s)

29 May 2024:

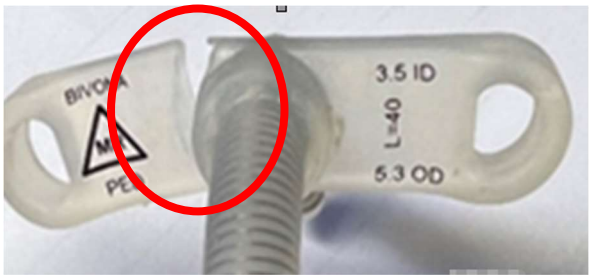
Dear Valued Bivona® Customers:

- Director of Biomedical Engineering
- Director of Nursing
- Director of Risk Management

Smiths Medical issuing this Urgent Field Safety Notice to notify you of a potential defect with the following Bivona® Neonatal/Pediatric and Adult Tracheostomy products listed in Attachment 1_Affected Product. This letter details the issue and the required steps for you to complete.

Issue:

Smiths Medical has identified that the securement flange of specific lots of the Bivona® Neonatal/Pediatric and Adult Tracheostomy products may tear because of a manufacturing defect. See picture below for an example of a torn flange.



Potential Risk:

If the flange on the item is torn or broken, the tracheostomy tube may not stay in position in the trachea. This can lead to tracheostomy displacement or decannulation. Either event may result in an inability to properly ventilate or protect the airway. Either can contribute to a catastrophic adverse event. To date, Smiths Medical has received thirty-five (35) reports of serious injury and one (1) death associated with this issue.

Affected Product:

Please see the affected item and lot numbers in Attachment 1_Affected Product List.

Smiths Medical Action:

Smiths Medical is sending this notification to all Bivona® customers who received products from Smiths Medical listed in Attachment 1_Affected Product. Smiths Medical will provide replacement product(s) and/or credit affected customers. Please contact your local representative with your certificate of destruction to coordinate the replacement/credit.

Customer 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:

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1. Check all inventory locations within your institution for the affected catalog numbers 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.

2. 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.

3. Complete and return the attached Customer Response Form to **smithsmedical3513@sedgwick.com** ***within 10 days of receipt*** to acknowledge your understanding of this notification. Please contact your local representative for assistance with replacement product and/or credit.

3. DISTRIBUTORS: If you have distributed potentially affected products to your customers, please immediately forward this notice to them. Request that they complete the response form and return it to **smithsmedical3513@sedgwick.com**

If you have any questions regarding product replacement and/or credit, please contact Smiths Customer Service below.

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	1-(866)-216-8806 or US: globalcomplaints@icumed.com	To report adverse events or product complaints
Customer Service	Customerservice@icumed.com 1-(800)-258-5361	Questions about your product replacement and/or credit

This notification is being performed with the knowledge of regulatory authorities, including the US Food and Drug Administration (FDA).

If you wish to contact the FDA regarding any adverse events or quality problems associated with this notice, use the following contact information.

- www.fda.gov/medwatch
- 1-(888)-INFO-FDA

Smiths Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,

Andy Mathein
Vice President of Quality

Enclosures:

- Customer Response Form
- Attachment 1_Affected Product