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URGENT MEDICAL DEVICE RECALL

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)

ARTG:397290
TGA Reference number: RC-2024-RN-00429-1

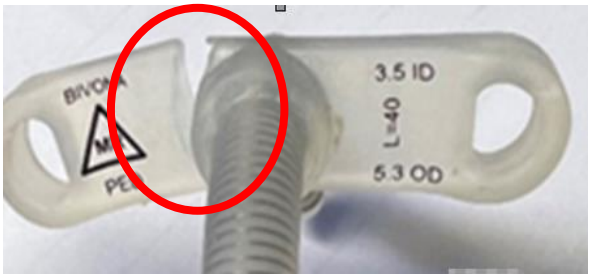
31 May 2024

Dear Valued Bivona® Customers:

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

Smiths Medical is issuing this Urgent medical device recall 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 (delivered since 2019) 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 issue a credit for all discarded products. Please contact regulatory.affairs@icumed.com with your acknowledgement of destruction to coordinate the credit.

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Customer Required Actions:

Please complete the following actions listed below:

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 regulatory.affairs@icumed.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.

4. 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 regulatory.affairs@icumed.com.

5. CLINICIANS: If the device is currently in-situ for a patient currently being ventilated, the clinician should consider the risks and benefits of leaving the device in situ (for a maximum of 29 days as per the intended purpose) versus explantation and exchange for an alternative product.

6. CLINICIANS: If, due to extenuating circumstances, an alternative device cannot be used, all instructions, including warnings and cautions contained in the Instructions for Use Documentation must be followed with heightened awareness when checking the device prior to use, securing and checking devices in use.

If you have any questions regarding product replacement and/or credit, please contact Smith's Customer Service on 1800 654 949

This notification is being performed with the knowledge of the Therapeutic Goods Administration (TGA).

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,

Dr. George Koumantakis
ICU Medical Australia

Enclosures:

- Customer Response Form
- Attachment 1_Affected Product