

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:

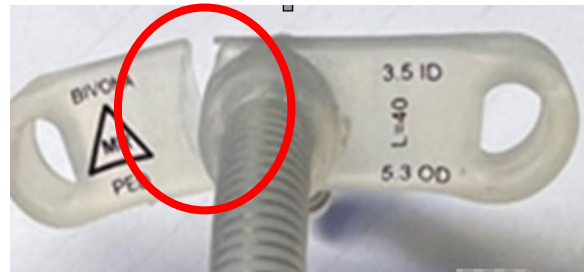
Dear Valued Bivona® Customers:

- 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 that were distributed to Malaysia 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:

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 asiaquality@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.

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

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

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,


 29 May 2024
 Leodigard Montefalcon
 Senior Quality Assurance Manager - Asia

Enclosures:

- Customer Response Form
- Attachment1 - Affected Products List

Attachment 1 – Affected Products List

Product Description	List Numbers	Lot/Serial Numbers
Aire-Cuf Trachy Tube 6.0mm Mid-Range	750160	4335536
Aire-Cuf Trachy Tube 7.0mm Mid-Range	750170	4122529, 4185497
Aire-Cuf Trachy Tube 8.0mm Mid-Range	750180	4105325
2.5 Uncuffed Neonatal Tracheostomy Tube	60SN025	3868323, 3955794, 4322691
3.0 Uncuffed Neonatal Tracheostomy Tube	60SN030	3952375, 3959303, 3965337, 3965338, 4110469, 4209588
3.5 Uncuffed Neonatal Tracheostomy Tube	60SN035	3952357, 3952358, 3962568, 3991208, 4196299, 4206845, 4276484, 4322692, 4348748, 4389930
4.0 Uncuffed Neonatal Tracheostomy Tube	60SN040	3868285, 3907976, 3952368, 3952369, 4233982
2.5 Uncuffed Pediatric Tracheostomy Tube	60SP025	3952363, 4223743
3.0 Uncuffed Pediatric Tracheostomy Tube	60SP030	3853492, 4021423, 4083929, 4086024, 4204828, 4209590, 4254287, 4283260
3.5 Uncuffed Pediatric Tracheostomy Tube	60SP035	3853493, 3868229, 4012662, 4034947, 4077085, 4095919, 4107587, 4156660, 4161959, 4161960, 4176210, 4212794, 4237398, 4240167, 4254288, 4260080, 4276485, 4289500, 4322693, 4322695, 4351253, 4369624, 4393429
4.0 Uncuffed Pediatric Tracheostomy Tube	60SP040	3840061, 3853495, 3853496, 3861152, 4015605, 4015608, 4089288, 4113097, 4134011, 4151024, 4153604, 4159987, 4185438, 4196301, 4218725, 4221362, 4237399, 4240168, 4273444, 4352806, 4369630, 4374485
4.5 Uncuffed Pediatric Tracheostomy Tube	60SP045	3868194, 3955808, 4056253, 4066297, 4080782, 4161995, 4168146, 4204830, 4286826, 4335092, 4345047, 4357228
5.0 Uncuffed Pediatric Tracheostomy Tube	60SP050	3952383, 4015613, 4040760, 4216340, 4218726, 4233986, 4254292, 4273445, 4279351, 4369627
5.5 Uncuffed Pediatric Tracheostomy Tube	60SP055	3868322, 3901294, 4223744, 4279352
2.5mm Aire-Cuf Pediatric Tracheostomy Tube	65SP025	4344963
3.0mm Aire-Cuf Pediatric Tracheostomy Tube	65SP030	4334872
3.5mm Aire-Cuf Pediatric Tracheostomy Tube	65SP035	4139008, 4344966, 4362879, 4380067, 4388094

4.0mm Aire-Cuf Pediatric Tracheostomy Tube	65SP040	4348396, 4348397
4.5mm Aire-Cuf Pediatric Tracheostomy Tube	65SP045	4122433, 4348399, 4399124
5.0mm Aire-Cuf Pediatric Tracheostomy Tube	65SP050	4139012, 4351232, 4352754
5.5mm Aire-Cuf Pediatric Tracheostomy Tube	65SP055	4348403, 4353066
2.5mm TTS Cuffed Pediatric Tracheostomy Tube	67SP025	4352776
3.0mm TTS Cuffed Pediatric Tracheostomy Tube	67SP030	4374423
3.5mm TTS Cuffed Pediatric Tracheostomy Tube	67SP035	4147982, 4153606, 4327927, 4331584, 4348433, 4352779, 4362880
4.0mm TTS Cuffed Pediatric Tracheostomy Tube	67SP040	4328229
4.5mm TTS Cuffed Pediatric Tracheostomy Tube	67SP045	3864230, 4334966
5.0mm TTS Cuffed Pediatric Tracheostomy Tube	67SP050	4286799, 4328231, 4334967
5.5mm TTS Cuffed Pediatric Tracheostomy Tube	67SP055	3874309

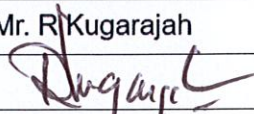
URGENT MEDICAL DEVICE NOTIFICATION: RESPONSE FORM

**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

Check your inventory and complete the information below, even if you do not have the affected product.

Complete this form and email to asiaquality@icumed.com.

Name of Hospital / Facility	Primed Medical Sdn Bhd
Hospital / Facility Address	No. 15, Jalan DBP 3, Dolomite Business Park, 68100 Batu Cave, Selangor Darul Ehsan
Telephone Number	+603-6185 1824
Name and Title of Person Completing this Form	Mr. R. Kugarajah
Signature of Person Completing this Form	
Date	7th June 2024
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

YES, I have affected product, I have notified users in my facility and I have followed the instructions provided to me to destroy all affected items. (complete and return this form via e-mail above). Please fill out the table below.

I have NO affected product (complete and return this form to Sedgwick via the fax/e-mail above)

Devices transferred/no longer owned; please indicate new owner contact information:

- Business Name: _____
- Address/City/State/ZIP: _____
- Contact Name: _____
- Contact Phone/E-mail Address: _____

• Have you distributed the product further to the retail level? YES NO

If you have distributed the product further, **please provide the list of your retail customers, inclusive of customer name, address, city, state, zip code, telephone number and quantity of product distributed along with your completed response form to the contact information listed above** so Smiths Medical can verify effectiveness of the recall notification to the appropriate level.

Adverse events and complaints associated with the use of these products should be reported and emailed to Smiths Medical's Global Complaint Management Department (globalcomplaints@icumed.com) or to the FDA at the contact information provided with this notification.

Lot Number	Quantity in inventory	Quantity to be Destroyed	<u>Date of Destruction</u>	Wholesaler/Distributor Name If you purchased from Wholesalers/Distributors include name, address, city, state, zip, quantity from each, and invoice number. If you purchased directly from Smiths Medical leave this section blank.	PO #	Invoice #	Debit Memo #
				1			
				2			
				3			