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**SMITHS MEDICAL ISSUES URGENT DEVICE RECALL OF CERTAIN BIVONA®
NEONATAL, PEDIATRIC, AND FLEXTEND TRACHEOSTOMY TUBES**

FOR IMMEDIATE RELEASE – ST. PAUL, Minn. – 22 December 2011 – Smiths Medical, a leading global medical device manufacturer, announced today that it is initiating a nationwide voluntary recall of Bivona® Neonatal, Pediatric and FlexTend™ Tracheostomy Tubes with integrated connector which is not designed to be used with a disconnect wedge. The FDA has been apprised of this action.

Smiths Medical is conducting this recall because some customers have experienced difficulty disconnecting accessories from the connectors of the Affected Tubes. In some cases, the customer was unable to disconnect the accessory or excessive force led to decannulation of the tube, and an emergency tracheostomy tube change was required. If the accessory is correctly connected to the Affected Tubes, then there will be no issue with disconnection. A copy of the customer notification letter, along with pictures to distinguish the affected tubes, is posted on the Smiths Medical website at <http://www.smiths-medical.com>.

Consumers who have the Affected Tubes should:

- 1) Identify all affected unused product in inventory and segregate it to a quarantine location.
- 2) Complete the Confirmation Form located at <http://www.smiths-medical.com> and return it by Fax to 219-989-7259 or by email to bivona.tr3@smiths-medical.com.
- 3) Upon receipt of your completed Confirmation Form, Customer Service will contact you with a Return Material Authorization Number (RMA#), and will schedule the shipment of a replacement Bivona® Neonatal, Pediatric and FlexTend™ Tracheostomy Tube. If you are opting to return the product, credit will be issued upon receipt of the returned product.

If an Affected Tube is currently in use with a patient, there is no evidence to suggest that immediate removal of the Tracheostomy Tube is necessary. Please visit Smiths Medical's website at <http://www.smiths-medical.com/education-resources/videos/airway/index.html> for a video demonstration on how to properly connect and disconnect accessories from the Affected Tubes.

Details of Affected Devices:

Bivona® Neonatal, Pediatric and FlexTend™ Tracheostomy Tubes
Lot Numbers 1631477 through 1923406

Reorder Numbers

<u>Reorder Number</u>	<u>Product Name</u>	<u>Size</u>
60N025	Bivona® Uncuffed Neonatal Tracheostomy Tube	2.5
60N030	Bivona® Uncuffed Neonatal Tracheostomy Tube	3.0
60N035	Bivona® Uncuffed Neonatal Tracheostomy Tube	3.5
60N040	Bivona® Uncuffed Neonatal Tracheostomy Tube	4.0
60NFP25	Bivona® Uncuffed Neonatal FlexTend™ Plus Tracheostomy Tube	2.5
60NFP30	Bivona® Uncuffed Neonatal FlexTend™ Plus Tracheostomy Tube	3.0
60NFP35	Bivona® Uncuffed Neonatal FlexTend™ Plus Tracheostomy Tube	3.5

Reorder Number	Product Name	Size
60NFP40	Bivona® Uncuffed Neonatal FlexTend™ Plus Tracheostomy Tube	4.0
60NFPS25	Bivona® Uncuffed Neonatal FlexTend™ Plus Tracheostomy Tube	2.5
60NFPS30	Bivona® Uncuffed Neonatal FlexTend™ Plus Tracheostomy Tube	3.0
60NFPS35	Bivona® Uncuffed Neonatal FlexTend™ Plus Tracheostomy Tube	3.5
60NFPS40	Bivona® Uncuffed Neonatal FlexTend™ Plus Tracheostomy Tube	4.0
60P025	Bivona® Uncuffed Pediatric Tracheostomy Tube	2.5
60P030	Bivona® Uncuffed Pediatric Tracheostomy Tube	3.0
60P035	Bivona® Uncuffed Pediatric Tracheostomy Tube	3.5
60P040	Bivona® Uncuffed Pediatric Tracheostomy Tube	4.0
60P045	Bivona® Uncuffed Pediatric Tracheostomy Tube	4.5
60P050	Bivona® Uncuffed Pediatric Tracheostomy Tube	5.0
60P055	Bivona® Uncuffed Pediatric Tracheostomy Tube	5.5
60PPF40	Bivona® Uncuffed Pediatric FlexTend™ Plus Extra Length Tracheostomy Tube	4.0
60PPF45	Bivona® Uncuffed Pediatric FlexTend™ Plus Extra Length Tracheostomy Tube	4.5
60PPF50	Bivona® Uncuffed Pediatric FlexTend™ Plus Extra Length Tracheostomy Tube	5.0
60PPF55	Bivona® Uncuffed Pediatric FlexTend™ Plus Extra Length Tracheostomy Tube	5.5
60PPF60	Bivona® Uncuffed Pediatric FlexTend™ Plus Extra Length Tracheostomy Tube	6.0
60PFPS40	Bivona® Uncuffed Pediatric FlexTend™ Plus Extra Length Tracheostomy Tube	4.0
60PFPS45	Bivona® Uncuffed Pediatric FlexTend™ Plus Extra Length Tracheostomy Tube	4.5
60PFPS50	Bivona® Uncuffed Pediatric FlexTend™ Plus Extra Length Tracheostomy Tube	5.0
60PFPS55	Bivona® Uncuffed Pediatric FlexTend™ Plus Extra Length Tracheostomy Tube	5.5
60PFPS60	Bivona® Uncuffed Pediatric FlexTend™ Plus Extra Length Tracheostomy Tube	6.0
60PFS25	Bivona® Uncuffed Pediatric FlexTend™ Plus Standard Tracheostomy Tube	2.5
60PFS30	Bivona® Uncuffed Pediatric FlexTend™ Plus Standard Tracheostomy Tube	3.0
60PFS35	Bivona® Uncuffed Pediatric FlexTend™ Plus Standard Tracheostomy Tube	3.5
60PFS40	Bivona® Uncuffed Pediatric FlexTend™ Plus Standard Tracheostomy Tube	4.0
60PFS45	Bivona® Uncuffed Pediatric FlexTend™ Plus Standard Tracheostomy Tube	4.5
60PFS50	Bivona® Uncuffed Pediatric FlexTend™ Plus Standard Tracheostomy Tube	5.0
60PFS55	Bivona® Uncuffed Pediatric FlexTend™ Plus Standard Tracheostomy Tube	5.5
60PFSS25	Bivona® Uncuffed Pediatric FlexTend™ Plus Standard Tracheostomy Tube	2.5
60PFSS30	Bivona® Uncuffed Pediatric FlexTend™ Plus Standard Tracheostomy Tube	3.0
60PFSS35	Bivona® Uncuffed Pediatric FlexTend™ Plus Standard Tracheostomy Tube	3.5
60PFSS40	Bivona® Uncuffed Pediatric FlexTend™ Plus Standard Tracheostomy Tube	4.0
60PFSS45	Bivona® Uncuffed Pediatric FlexTend™ Plus Standard Tracheostomy Tube	4.5
60PFSS50	Bivona® Uncuffed Pediatric FlexTend™ Plus Standard Tracheostomy Tube	5.0
60PFSS55	Bivona® Uncuffed Pediatric FlexTend™ Plus Standard Tracheostomy Tube	5.5
60SN025	Bivona® Uncuffed Neonatal Tracheostomy Tube	2.5
60SN030	Bivona® Uncuffed Neonatal Tracheostomy Tube	3.0
60SN035	Bivona® Uncuffed Neonatal Tracheostomy Tube	3.5
60SN040	Bivona® Uncuffed Neonatal Tracheostomy Tube	4.0
60SP025	Bivona® Uncuffed Pediatric Tracheostomy Tube	2.5
60SP030	Bivona® Uncuffed Pediatric Tracheostomy Tube	3.0
60SP035	Bivona® Uncuffed Pediatric Tracheostomy Tube	3.5
60SP040	Bivona® Uncuffed Pediatric Tracheostomy Tube	4.0
60SP045	Bivona® Uncuffed Pediatric Tracheostomy Tube	4.5
60SP050	Bivona® Uncuffed Pediatric Tracheostomy Tube	5.0
60SP055	Bivona® Uncuffed Pediatric Tracheostomy Tube	5.5
65N025	Bivona® Aire-Cuf® Neonatal Tracheostomy Tube	2.5
65N030	Bivona® Aire-Cuf® Neonatal Tracheostomy Tube	3.0
65N035	Bivona® Aire-Cuf® Neonatal Tracheostomy Tube	3.5
65N040	Bivona® Aire-Cuf® Neonatal Tracheostomy Tube	4.0
65P025	Bivona® Aire-Cuf® Pediatric Tracheostomy Tube	2.5

Reorder Number	Product Name	Size
65P030	Bivona® Aire-Cuf® Pediatric Tracheostomy Tube	3.0
65P035	Bivona® Aire-Cuf® Pediatric Tracheostomy Tube	3.5
65P040	Bivona® Aire-Cuf® Pediatric Tracheostomy Tube	4.0
65P045	Bivona® Aire-Cuf® Pediatric Tracheostomy Tube	4.5
65P050	Bivona® Aire-Cuf® Pediatric Tracheostomy Tube	5.0
65P055	Bivona® Aire-Cuf® Pediatric Tracheostomy Tube	5.5
65SN025	Bivona® Aire-Cuf® Neonatal Tracheostomy Tube	2.5
65SN030	Bivona® Aire-Cuf® Neonatal Tracheostomy Tube	3.0
65SN035	Bivona® Aire-Cuf® Neonatal Tracheostomy Tube	3.5
65SN040	Bivona® Aire-Cuf® Neonatal Tracheostomy Tube	4.0
65SP025	Bivona® Aire-Cuf® Pediatric Tracheostomy Tube	2.5
65SP030	Bivona® Aire-Cuf® Pediatric Tracheostomy Tube	3.0
65SP035	Bivona® Aire-Cuf® Pediatric Tracheostomy Tube	3.5
65SP040	Bivona® Aire-Cuf® Pediatric Tracheostomy Tube	4.0
65SP045	Bivona® Aire-Cuf® Pediatric Tracheostomy Tube	4.5
65SP050	Bivona® Aire-Cuf® Pediatric Tracheostomy Tube	5.0
65SP055	Bivona® Aire-Cuf® Pediatric Tracheostomy Tube	5.5
67N025	Bivona® TTS™ Cuffed Neonatal Tracheostomy Tube	2.5
67N030	Bivona® TTS™ Cuffed Neonatal Tracheostomy Tube	3.0
67N035	Bivona® TTS™ Cuffed Neonatal Tracheostomy Tube	3.5
67N040	Bivona® TTS™ Cuffed Neonatal Tracheostomy Tube	4.0
67P025	Bivona® TTS™ Cuffed Pediatric Tracheostomy Tube	2.5
67P030	Bivona® TTS™ Cuffed Pediatric Tracheostomy Tube	3.0
67P035	Bivona® TTS™ Cuffed Pediatric Tracheostomy Tube	3.5
67P040	Bivona® TTS™ Cuffed Pediatric Tracheostomy Tube	4.0
67P045	Bivona® TTS™ Cuffed Pediatric Tracheostomy Tube	4.5
67P050	Bivona® TTS™ Cuffed Pediatric Tracheostomy Tube	5.0
67P055	Bivona® TTS™ Cuffed Pediatric Tracheostomy Tube	5.5
67SN025	Bivona® TTS™ Cuffed Neonatal Tracheostomy Tube	2.5
67SN030	Bivona® TTS™ Cuffed Neonatal Tracheostomy Tube	3.0
67SN035	Bivona® TTS™ Cuffed Neonatal Tracheostomy Tube	3.5
67SN040	Bivona® TTS™ Cuffed Neonatal Tracheostomy Tube	4.0
67SP025	Bivona® TTS™ Cuffed Pediatric Tracheostomy Tube	2.5
67SP030	Bivona® TTS™ Cuffed Pediatric Tracheostomy Tube	3.0
67SP035	Bivona® TTS™ Cuffed Pediatric Tracheostomy Tube	3.5
67SP040	Bivona® TTS™ Cuffed Pediatric Tracheostomy Tube	4.0
67SP045	Bivona® TTS™ Cuffed Pediatric Tracheostomy Tube	4.5
67SP050	Bivona® TTS™ Cuffed Pediatric Tracheostomy Tube	5.0
67SP055	Bivona® TTS™ Cuffed Pediatric Tracheostomy Tube	5.5

Smiths Medical is notifying its customers through the U.S. mail. Recipients of the Urgent Field Safety Notice who have distributed the Affected Tubes to other persons or facilities should promptly forward a copy of the Urgent Field Safety Notice accordingly.

For questions regarding this Recall, customers should contact:

Smiths Medical Customer Service (Monday – Friday 8am – 8pm CST)
800-258-5361, Option 1
bivona.tr3@smiths-medical.com

Customers should report any issues with the Bivona® Neonatal, Pediatric and FlexTend Tracheostomy Tubes to Smiths Medical's Complaints Department at 1-866-216-8806.

Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online at www.fda.gov/MedWatch/report.htm
- Regular Mail; use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm
- Fax 1-800-FDA-0178.

About Smiths Medical

Smiths Medical www.smiths-medical.com is a leading supplier of specialized medical devices and equipment for global markets, focusing on the medication delivery, vital care and safety devices market segments. It is part of **Smiths Group** www.smiths.com, a global leader in applying advanced technologies for markets in threat and contraband detection, energy, medical devices, communications and engineered components. **Smiths Group** employs around 22,000 people in more than 50 countries.