

Smiths Medical ASD, Inc
5700 West 23rd Avenue
Gary, IN 46406

UPDATED URGENT FIELD SAFETY NOTICE

Certain Lot Numbers of Bivona® Neonatal, Pediatric and Flexend Tracheostomy Tubes

Affected Devices: Bivona® Neonatal, Pediatric and Flexend Tracheostomy Tubes

Type of Action: Urgent Field Safety Corrective Action - **RECALL**

Date: December 22, 2011

Attention: **Hospital:** NICU Director, PICU Director, Respiratory Director, O/R Manager, Radiology Director, Dept. of Surgery/ Otolaryngology Chairman, and Tracheostomy Resource Nurse

Alternate Care: Purchasing Manager, Cardio-Pulmonary Manager, ENT Services, and Clinical Education/ Respiratory Director

Distributor

Details of Affected Devices:

Bivona® Neonatal, Pediatric and Flexend Tracheostomy Tubes

Only Lot Numbers 1631477 through 1923406

Reorder Numbers:

60N025	60PFP45	60PFSS45	65P035	67P025
60N030	60PFP50	60PFSS50	65P040	67P030
60N035	60PFP55	60PFSS55	65P045	67P035
60N040	60PFP60	60SN025	65P050	67P040
60NFP25	60PFPS40	60SN030	65P055	67P045
60NFP30	60PFPS45	60SN035	65SN025	67P050
60NFP35	60PFPS50	60SN040	65SN030	67P055
60NFP40	60PFPS55	60SP025	65SN035	67SN025
60NFP525	60PFPS60	60SP030	65SN040	67SN030
60NFP530	60PFS25	60SP035	65SP025	67SN035
60NFP535	60PFS30	60SP040	65SP030	67SN040
60NFP540	60PFS35	60SP045	65SP035	67SP025
60P025	60PFS40	60SP050	65SP040	67SP030
60P030	60PFS45	60SP055	65SP045	67SP035
60P035	60PFS50	65N025	65SP050	67SP040
60P040	60PFS55	65N030	65SP055	67SP045
60P045	60PFSS25	65N035	67N025	67SP050
60P050	60PFSS30	65N040	67N030	67SP055
60P055	60PFSS35	65P025	67N035	
60PFP40	60PFSS40	65P030	67N040	

Details of Urgent Safety Alert:

Based on the information gathered from a continued investigation, Smiths Medical has expanded its original Urgent Field Safety Notice, dated November 28, 2011, to voluntarily recall all Bivona® Neonatal, Pediatric and Flexend Tracheostomy Tubes, **Lot Numbers 1631477**

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through 1923406, with the integrated connector that does not require use of a disconnect wedge (“Affected Tubes”). (See Photo A below).

Smiths Medical has become aware of a small number of complaints of customers experiencing difficulty disconnecting accessories from the connectors of the Affected Tubes. In some cases, the customer was unable to disconnect the accessory or excessive force lead 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.**

Design enhancements were introduced to the Bivona® Neonatal, Pediatric and Flextend Tracheostomy Tubes in November, 2010 that helped to increase the ease of use with connections/disconnections. The latest version of the Bivona® Tracheostomy Tubes includes a disconnection surface and a disconnect wedge to assist in the disconnection of accessories. (See Photo A below)

Photo A: Neonatal and Pediatric Tracheostomy Tubes

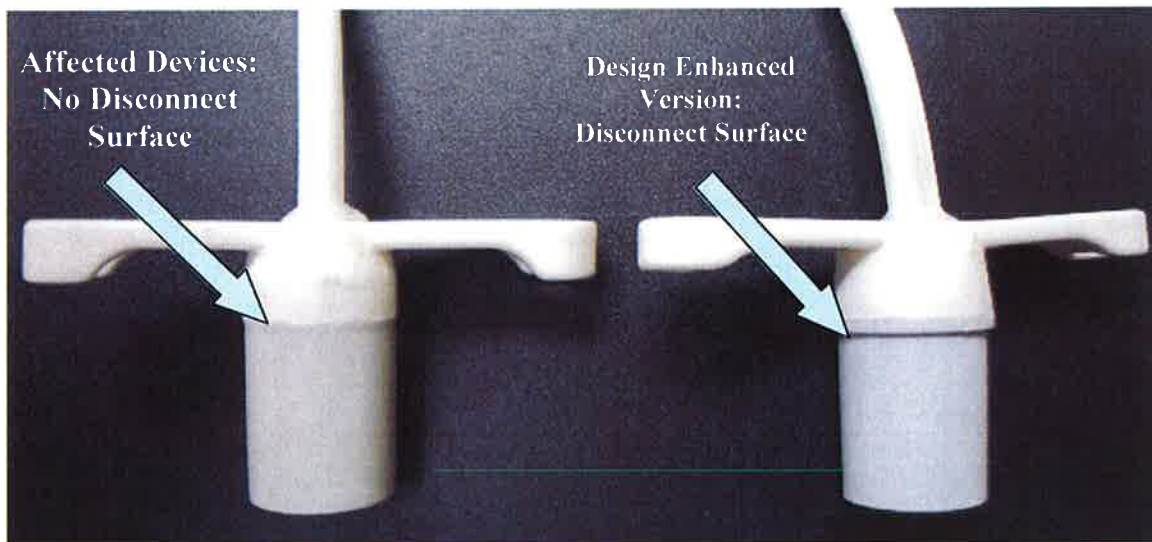


Photo B: Flextend Tracheostomy Tubes



Advice on Action to be Taken By the User:

- 1) Identify all affected unused product in inventory and segregate it to a quarantine location.
- 2) Complete the attached Confirmation Form 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 Flexend 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. 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. This information is intended to supplement the Instructions for Use provided with these products – it is not intended to replace the Instructions.

If you or your facility has distributed the affected Tubes to other persons or facilities, please promptly forward the recipients a copy of this Urgent Field Safety Notice.

Any adverse reactions experienced with the use of these products and/ or quality problems may also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088 (1-800-332-1088), by Fax at 1-800-FDA-0178 (1-800-332-0178), by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852, or online at www.fda.gov/medwatch.

If you should have any questions regarding this Recall or Urgent Field Safety Notice, please contact us at 800-258-5361, Option 1.

Smiths Medical is committed to providing quality products and service to its customers. We apologize for the inconvenience this situation may have caused.

Sincerely,



Dana Knight
Manager, Quality Systems
Smiths Medical ASD, Inc.

Enclosures:

Attachment 1 Urgent Field Safety Notice Confirmation Form

Attachment 1

**URGENT SAFETY ALERT CONFIRMATION FORM
for Bivona® Neonatal, Pediatric and Flextend Tracheostomy Tubes (TR3 Version)**

Please complete and return this Form by Fax to 219.989.7259 or by sending an electronic copy via email to bivona.tr3@smiths-medical.com.

<input type="checkbox"/>	I DO NOT have affected Bivona® Neonatal, Pediatric and Flextend Tracheostomy Tubes remaining in inventory. All have been used or discarded.
Option 1: Exchanging of Product	
<input type="checkbox"/>	I have unopened, unused product that I would like to exchange for the equivalent enhanced design version. (Please provide part numbers and quantities on the back side of this Confirmation Form)
Option 2: Returning of Product	
<input type="checkbox"/>	I have unopened, unused product that I would like to return for credit. (Please provide part numbers and quantities on the back side of this Confirmation Form)

Printed Name: _____ Department: _____

Signature: _____ Date: _____

Facility Name: _____ Facility Address: _____

Shipping Address: _____

Phone Number: () - Ext: _____ Email: _____

