Medical Device Alert

Ref: MDA/2012/002 Issued: 19 January 2012 at 14:30

Device

Tracheostomy tubes: Bivona® Neonatal, Pediatric and Flextend.

Manufactured by Smiths Medical.

Lot numbers from 1631477 to 1923406 inclusive.

Problem

Incorrectly connected accessories may be difficult to remove, requiring excessive force to disconnect. This may cause the tube to dislodge, requiring it to be changed.

The manufacturer has initiated a recall of affected tubes.

The manufacturer issued a Field Safety Notice (FSN) – dated 15 November 2011 (see appendix 2) – but has not had confirmation from all users that they have received and acted on this information.

Action by

All staff responsible for the care of neonatal and paediatric patients with tracheostomy tubes.

Personnel involved in the purchase, supply and distribution of these devices.

Action

- See appendix 1 for affected reorder numbers, and NHS supply chain codes where applicable.
- Locate and quarantine all unused affected devices.
- Complete and return the Smiths Medical confirmation form, **even if you no longer have affected units in stock**.
- Return all unused affected devices as described in the Field Safety Notice issued by Smiths Medical.

For patients with affected tubes in situ:

- Review the advice on correct use provided in the 'Customer Information Bulletin' (in the FSN) and "Tracheostomy – Neo-Pedi" guidance video on the Smiths Medical website.

CAS deadlines

Action underway: 02 February 2012

Action complete: 19 March 2012

Contact

Manufacturer
Philip York, Smiths Medical
Tel: 01923 241 411
Fax: 01233 722 153
Email: ukcs@smiths-medical.com

Device

Only devices intended for neonatal and paediatric use are affected.

Only tubes with an integrated connector that does not allow for use of a disconnect wedge (“TR3”) are affected.

Examples of accessories that can be used with the affected tubes include: speaking valves, heat moisture exchangers, and breathing circuit connectors.

A design modification was implemented in November 2010 to address this problem.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- Health Protection Agency (HPA) (Directors)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E departments
- Ambulance staff
- Anaesthetists
- Clinical governance leads
- Day surgery units
- ENT departments
- ENT medical staff
- Equipment stores
- Health and safety managers
- Medical directors
- Neonatology departments
- Paediatric intensive care units
- Paediatric wards
- Paediatrics departments
- Paramedics
- Purchasing managers
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Supplies managers
- Theatres

Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Community children’s nurses
- Community hospitals
- Community nurses
- District nurses

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Paediatric hospices
- Hospitals in the independent sector
- Independent treatment centres

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer
Philip York
Smiths Medical
1500 Eureka Park
Lower Pemberton, Ashford
Kent TN25 4BF

Tel: 01923 241 411
Fax: 01233 722 153

Email: ukcs@smiths-medical.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/002** or **2011/011/011/081/005**

Technical aspects
Emma Rooke or Douglas McIvor
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6609 / 7193
Fax: 020 8754 3965

Email: emma.rooke@mhra.gsi.gov.uk
douglas.mcivor@mhra.gsi.gov.uk

Clinical aspects
Dr Nicola Lennard
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7126
Fax: 020 8754 3965

Email: nicola.lennard@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic
Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

Appendix 1

The following Smiths reorder numbers are affected, with NHS Supply Chain Codes (England only) where relevant.

Smiths reorder number	NHS Supply Chain code
60N025	FDG249
60N030	FDG250
60N035	FDG251
60N040	FDG252
60NFP25	FDG590
60NFP30	FDG591
60NFP35	FDG592
60NFP40	FDG593
60NFPS25	N/A
60NFPS30	N/A
60NFPS35	N/A
60NFPS40	N/A
60P025	FDG253
60P030	FDG254
60P035	FDG255
60P040	FDG256
60P045	FDG257
60P050	FDG258
60P055	FDG259
60PFP40	N/A
60PFP45	N/A
60PFP50	N/A
60PFP55	N/A
60PFP60	N/A
60PFPS40	N/A
60PFPS45	N/A
60PFPS50	N/A
60PFPS55	N/A
60PFPS60	N/A
60PFS25	FDG260
60PFS30	FDG261
60PFS35	FDG262
60PFS40	FDG263
60PFS45	FDG264
60PFS50	FDG265
60PFS55	FDG266
60PFSS25	N/A
60PFSS30	N/A
60PFSS35	N/A
60PFSS40	N/A
60PFSS45	N/A
60PFSS50	N/A
60PFSS55	N/A
60SN025	N/A
60SN030	N/A
60SN035	N/A
60SN040	N/A
60SP025	N/A
60SP030	N/A
60SP035	N/A
60SP040	N/A
60SP045	N/A
60SP050	N/A
60SP055	N/A
65N025	N/A
65N030	N/A
65N035	N/A
65N040	N/A
65P025	N/A
65P030	N/A
65P035	N/A
65P040	N/A
65P045	N/A
65P050	N/A
65P055	N/A
65SN025	N/A
65SN030	N/A
65SN035	N/A
65SN040	N/A
65SP025	N/A
65SP030	N/A
65SP035	N/A
65SP040	N/A
65SP045	N/A
65SP050	N/A
65SP055	N/A
67N025	N/A
67N030	N/A
67N035	N/A
67N040	N/A
67P025	FDG272
67P030	FDG289
67P035	FDG365
67P040	FDG368
67P045	FDG369
67P050	FDG371
67P055	FDG372
67SN025	N/A
67SN030	N/A
67SN035	N/A
67SN040	N/A
67SP025	N/A
67SP030	N/A
67SP035	N/A
67SP040	N/A
67SP045	N/A
67SP050	N/A
67SP055	N/A

Appendix 2

smiths medical
bringing technology to life

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

URGENT FIELD SAFETY NOTICE

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

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

Type of Action: Urgent Field Safety Corrective Action - Recall

Date: 15 November 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

Details of Affected Devices:
Bivona® Neonatal, Pediatric and Flextend 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
60NFPS25	60PFPS60	60SP030	65SN040	67SN030
60NFPS30	60PFS25	60SP035	65SP025	67SN035
60NFPS35	60PFS30	60SP040	65SP030	67SN040
60NFPS40	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:
Smiths Medical is conducting a voluntary Field Safety Corrective Action for certain Lot Numbers of Bivona® Neonatal, Pediatric and Flextend Tracheostomy Tubes with the integrated connector that does not require use of a disconnect wedge ("Affected Tubes"). This voluntary Action is being conducted with the knowledge of the relevant Regulatory Agencies.

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)

This Urgent Field Safety Notice only applies to Affected Tubes with Lot Numbers 1631477 through 1923406. While Smiths Medical has received no reports of serious permanent injury or death, and not all customers will experience this issue, Smiths Medical is proactively recalling all unused Affected Tubes.

Photo A: Neonatal and Pediatric Tracheostomy Tubes

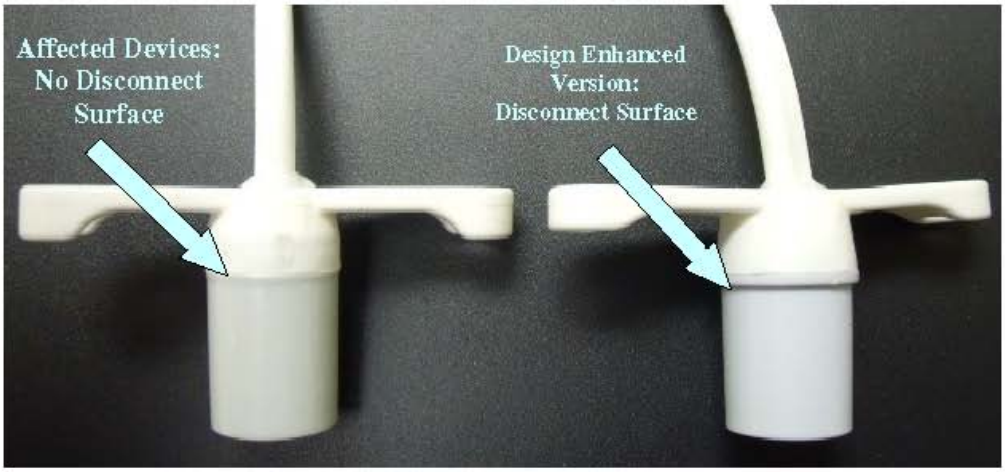


Photo B: Flextend Tracheostomy Tubes

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 +44 1233 722153 or by email to sauvanee.gan@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. Review the attached Customer Information Bulletin and / or 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.

If you should have any questions regarding this Urgent Field Safety Notice or the Customer Information Bulletin, please contact us at +44(0)1923 241411.

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 Customer Information Bulletin
Attachment 2 Urgent Field Safety Notice Confirmation Form

smiths medical
bringing technology to life

Smiths Medical ASD, Inc.
5700 West 23rd Avenue
Gary, IN 46406-2617 USA

CUSTOMER INFORMATION BULLETIN

Date of Issue: November 2011 **CIB Number:** 14112011

Products Affected: Bivona® Neonatal, Pediatric and Flextend Tracheostomy Tubes with the integrated connector that does not require use of a disconnect wedge

---

Smiths Medical has become aware of an issue with some customers experiencing difficulty disconnecting accessories from the 15mm connector of the Bivona® Neonatal, Pediatric and Flextend Tracheostomy Tubes ("Tracheostomy Tube") with the integrated connector that does not require use of a disconnect wedge.

Description of the Issue:
If the circuit or adapter is connected to the 15mm connector with excessive force, then the user may have difficulty or may be unable to disconnect the circuit or adapter from the 15mm connector. As a result, we recommend using a two-handed technique along with a twist and push/pull method to connect/disconnect the tube from the circuit or adapter (i.e., HME, speaking valve or breathing circuit connector).

It is important to follow the Instructions for Use supplied with these products, along with the directions below, for the safe and effective use of these products. Do not force the connection together too tightly as this may result in difficulty disconnecting the accessory from the 15mm connector.

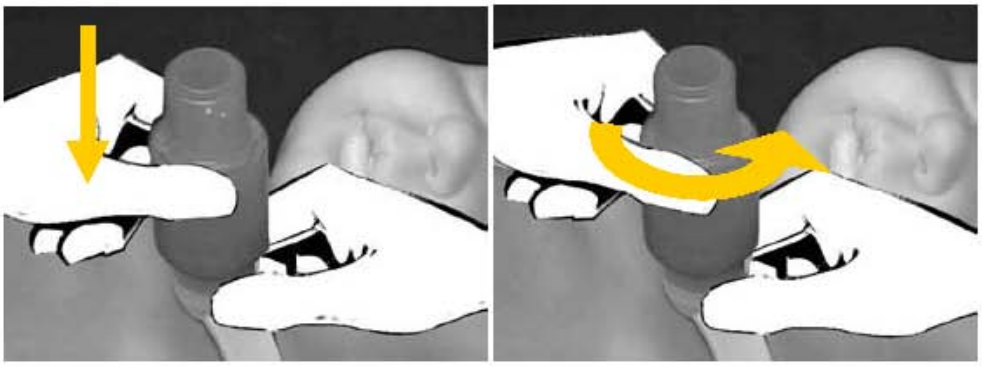
A video depicting this information is available for viewing on the Smiths Medical website at:
http://www.smiths-medical.com/education-resources/videos/airway/index.html

smiths medical
bringing technology to life

Connecting an Accessory to the 15mm Connector:

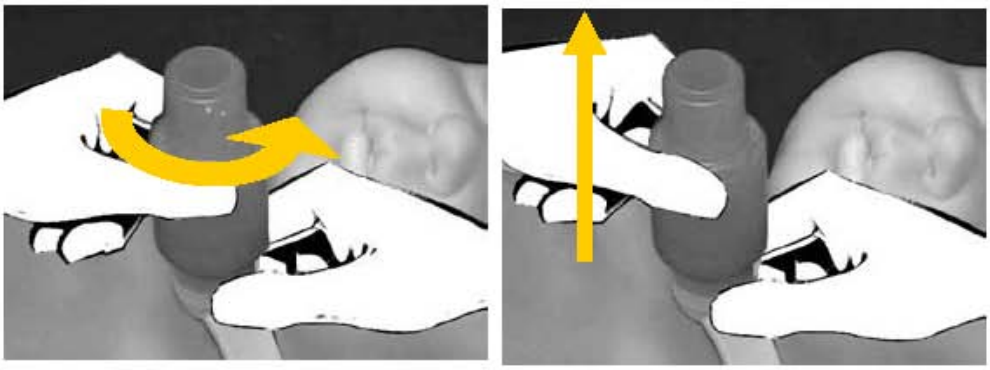
1. Put on non-sterile gloves.
2. Stabilize the base of the connector with one hand to minimize movement and trauma to the stoma.
3. Connect accessory to the top of tube's 15mm connector with your other hand.
4. Gently press downward until you feel resistance, and then continue to gently push down while simultaneously *twisting* the accessory with a quarter turn.

Note: Practice applying each accessory to the 15mm connector several times to gain experience with the appropriate downward pressure required.



Disconnecting:

1. Put on non-sterile gloves.
2. While firmly holding the base of the connector with one hand, use your other hand to gently rotate the accessory while pulling up, which loosens the seal.



Attachment 2

URGENT SAFETY ALERT CONFIRMATION FORM
for Bivona® Neonatal, Pediatric and Flextend Tracheostomy Tubes

Please complete and return this Form by Fax to +44 1233 722153 or by sending an electronic copy via email to sauvanee.gan@smiths-medical.com.

Section 1: Action Required By User	
☐	I have read and understood the Customer Information Bulletin provided with this Urgent Safety Alert.
☐	I have visited the Smiths Medical website and viewed the video on the proper disconnection of accessories (optional). http://www.smiths-medical.com/education-resources/videos/airway/index.html
Section 2: Returning of Product	
☐	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)
Section 3: No Affected Product	
☐	I have reviewed my inventory and have no unopened, unused product that is affected by this Urgent Safety Alert.
Section 4: Product Has Been Transferred to Another Facility	
☐	I have reviewed my inventory and determined that product affected by this Urgent Safety Alert has been transferred to another facility. Facility Name:

Printed Name: _____ Department: _____

Signature: _____ Date: _____

Facility Name: _____ Facility Address: _____

Shipping Address: _____

Phone Number: ( ) - Ext: Email: _____

1

Inventory of Affected Bivona® Neonatal, Pediatric and Flextend Tracheostomy Tubes

Return Product Requiring Replacement

Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	
Part Number		**Quantity**	

2