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

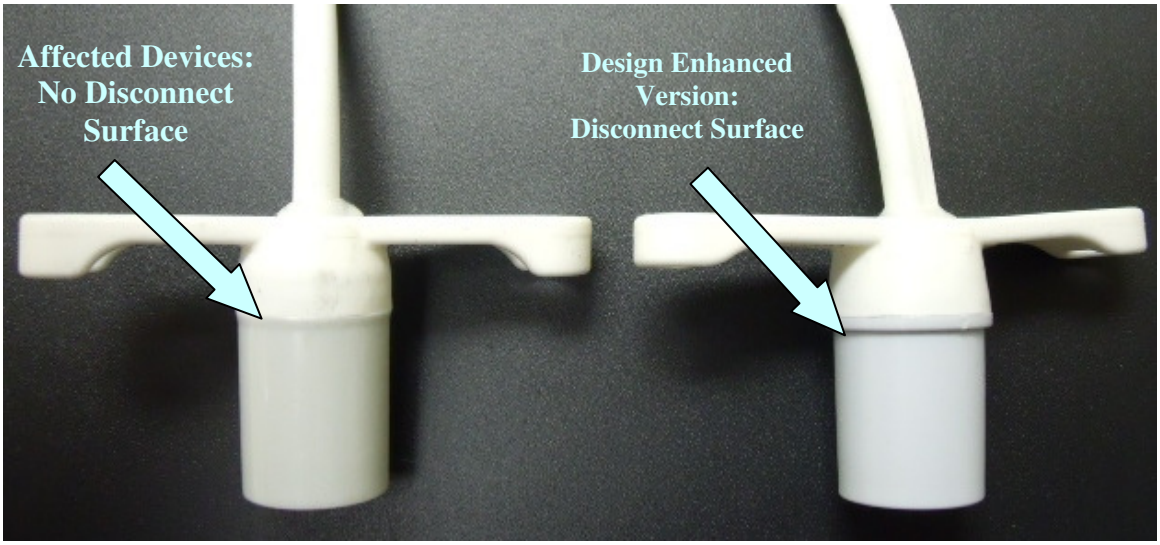
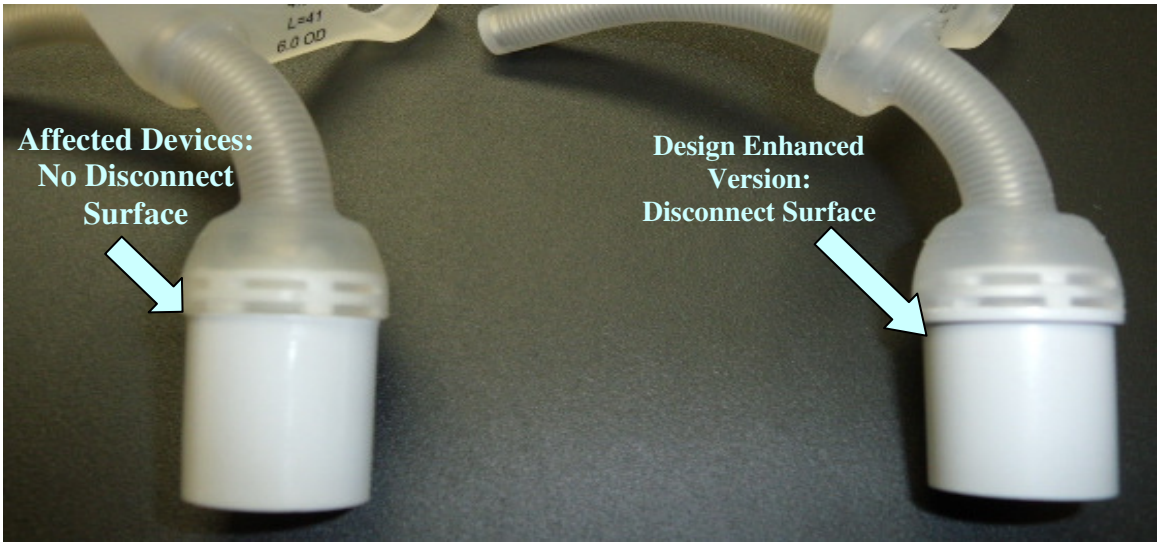


Photo B: Flextend Tracheostomy Tubes



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

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: Distributors

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

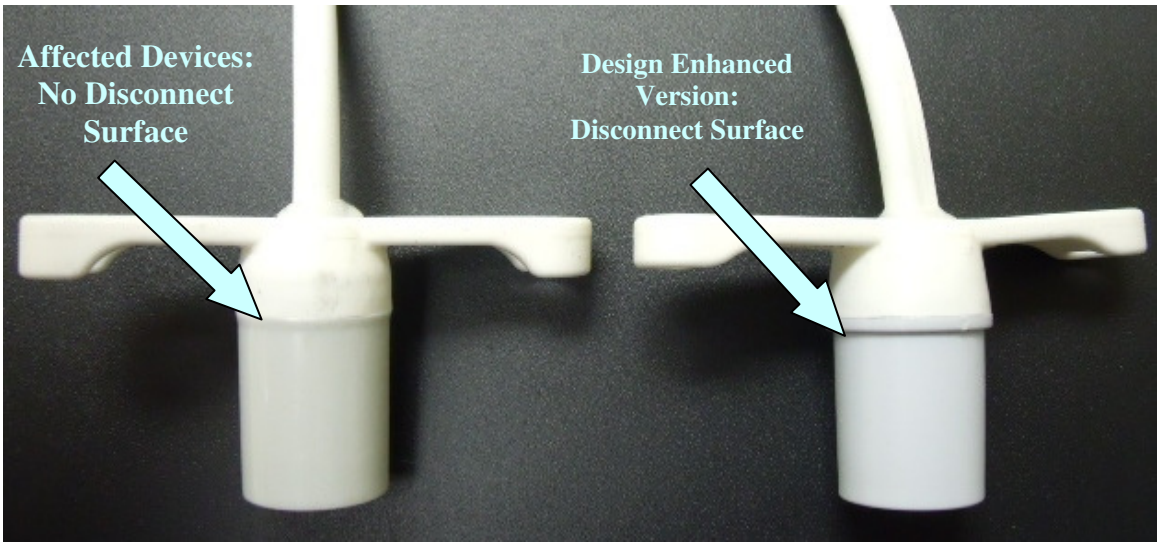
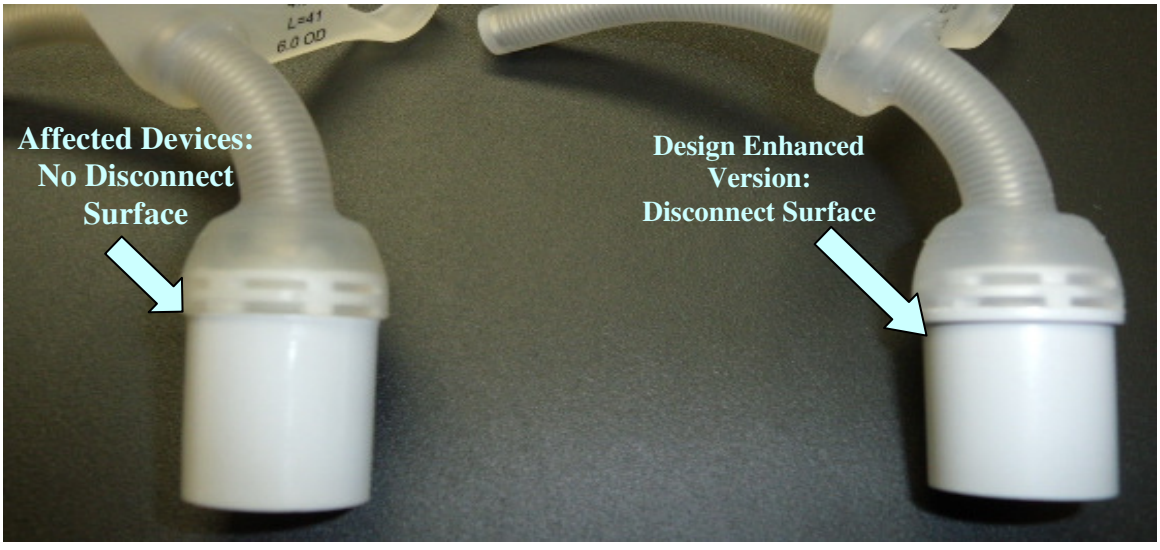


Photo B: Flextend Tracheostomy Tubes



Advice on Action to be Taken by Distributors:

1) Immediately stop distributing Affected Tubes and segregate inventory to a quarantine location.

2) Identify all customers that have received the affected Lot Numbers of Bivona® Neonatal, Pediatric and Flextend Tracheostomy Tubes. Promptly provide Smiths Medical with the list of customers, including contact details, so that Smiths Medical can notify the customers of this Urgent Field Safety Notice.

NOTE: If you do not have lot traceability, identify all customers that have received the affected reorder numbers from September 2009 to the current date.

3) Determine which option will be most appropriate for you:

Option 1: Exchanging of Product
Product will be exchanged for the equivalent enhanced design of the Bivona® Neonatal, Pediatric and Flextend Tracheostomy Tubes.

Option 2: Returning of Product
Product will be returned to Smiths Medical for credit. Complete the attached Confirmation Form and return it by Fax to Fax to +44 1233 722153 or by email to sauvanee.gan@smiths-medical.com.

4) 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 replacement Bivona® Neonatal, Pediatric and Flextend Tracheostomy Tubes. If you are opting to return the product, credit will be issued upon receipt of the returned product.

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 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

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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).

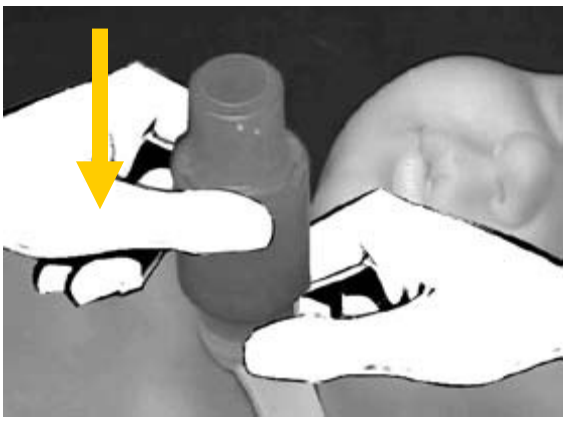
It is important to follow the Instructions for Use supplied with these products, along with the directions below, for the safe and effective use of these products. Do not force the connection together too tightly as this may result in difficulty disconnecting the accessory from the 15mm connector.

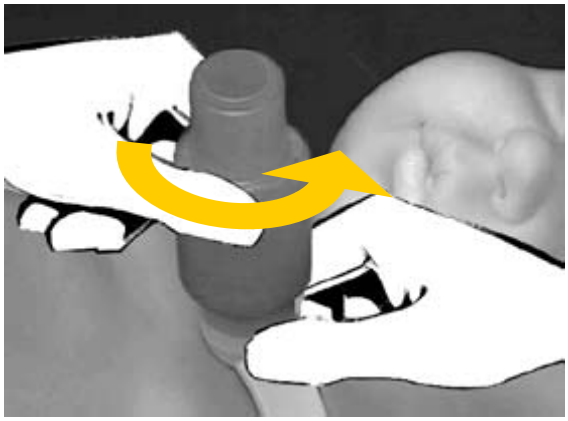
A video depicting this information is available for viewing on the Smiths Medical website at:
http://www.smiths-medical.com/education-resources/videos/airway/index.html

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.

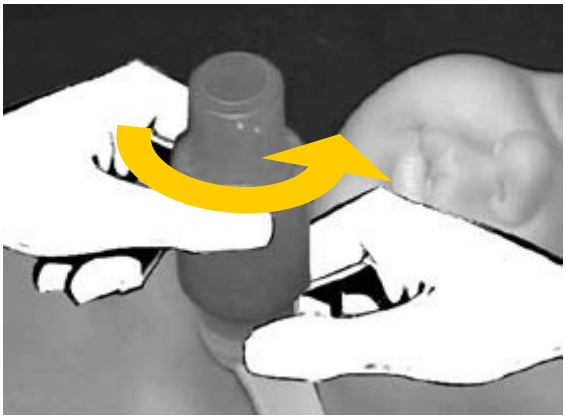
Note: Practice applying each accessory to the 15mm connector several times to gain experience with the appropriate downward pressure required.

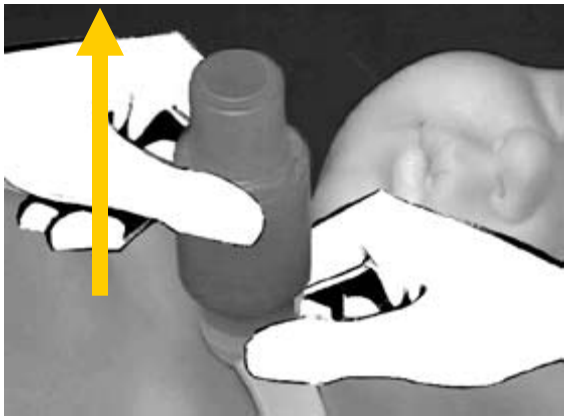




Disconnecting:

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: _____

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

Return Product Requiring Replacement

Part Number		**Quantity**	
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