Patient Safety Alert

Veterans Health Administration Warning System
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August 12, 2004

Item: **Shiley Tracheosoft XLT Extended Length Tracheostomy Tube and Cannula FDA Class I Recall.**

General Information: FDA and Nellcor/Tyco have issued a Class I (most serious) recall of the Shiley Tracheosoft XLT Extended Length Tracheostomy Tube and Cannula. The outer cannula may separate from the hub and neck flange allowing the outer cannula to travel farther into the patient's airway leading to obstruction of the airway and significantly interfering with breathing and ventilation.

Specific Incident: Nellcor/Tyco has received two reports in which the cannula separation was allegedly associated with patient deaths. This recall affects 73,355 disposable units that the company has shipped to the U.S. and international customers over the last four years.

Actions:

1. Patients with the affected models (see attached) should be contacted and arrangements made to exchange the equipment.
2. If you have the affected devices in stock work with your materials management (AMMS) to make sure that a recall package has been received. Follow the instructions in the package to receive credit for the recalled products.
3. If you have these devices in stock and did not receive a recall package from the company, contact Nellcor/Tyco Technical Services Department at 1-800-635-5267.
4. See attached information on comparable replacements from Smiths Medical Bivona® to the recalled products.

Source: FDA and Tyco Healthcare.

Contact: Bryanne Patail at the VA National Center for Patient Safety (NCPS) phone: (734) 930-5852.

U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Department of Health and Human Services

Medical Device Recalls
Class 1 Recall: Shiley Tracheosoft Tracheostomy Tube and Disposable Inner Cannula

See Related Information

Date Recall Initiated: July 8, 2004

Product: Shiley Tracheosoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula

Use: The device is an extended length cannula (tube) with accessory components used to provide an artificial airway to assist in the treatment of a variety of respiratory diseases and airway management in adults. The tube is inserted into a tracheostomy incision in a patient's neck and trachea. The tracheostomy tube is secured in place through the tube's hub and flange assembly with the use of a holder or neck strap.

Recalling Firm: Nellcor/Tyco Healthcare
4280 Hacienda Drive
Pleasanton, CA 94588-2719

Reason for Recall: The outer cannula may separate from the hub and neck flange allowing the outer cannula to travel farther into the patient's airway and significantly interfere with breathing and ventilation. This recall affects 73,355 disposable units that the firm has shipped to U.S. and international customers over the last four years.

Public Contact: James Bonds
Senior Director, Regulatory Affairs
925-463-4371
james.bonds@tycohealthcare.com

FDA District: San Francisco

FDA Comment: Failure of the tracheostomy tube can allow the tube to migrate, leading to obstruction of the airway and subsequent lack of ventilation. Airway obstruction or failure to ventilate can lead to permanent neurological injury or death. Class I recalls are the most serious type of recall and involve situations where there is a reasonable probability that use of the product will cause serious injury or death.

Pleasanton, CA – August 6, 2004 – On July 8, 2004, Nellcor/Tyco Healthcare, initiated a voluntary recall of the Shiley® TracheoSoft® XLT Extended Length Tracheostomy Tube. The Company has shipped 73,355 units over the last four years throughout the U.S. and Canada. This product can be used in the hospital or home-care environment to provide tracheal access for airway management. The recall was prompted by reports of the outer cannula separating from the swivel neck plate. While the number of customer reports of cannula separation is very low, if this failure mode does occur, the outer cannula could travel into the patient' s airway, potentially interfering with breathing or ventilation; which could result in serious injury or death.

Accordingly, in the interest of patient safety, our recall extends to all lots of the following products:

Model Number	Description
72110-050	Size 5, Proximal Extension, Uncuffed
72110-060	Size 6, Proximal Extension, Uncuffed
72110-070	Size 7, Proximal Extension, Uncuffed
72110-080	Size 8, Proximal Extension, Uncuffed
72120-050	Size 5, Proximal Extension, Cuffed
72120-060	Size 6, Proximal Extension, Cuffed
72120-070	Size 7, Proximal Extension, Cuffed
72120-080	Size 8, Proximal Extension, Cuffed
73110-050	Size 5, Distal Extension, Uncuffed
73110-060	Size 6, Distal Extension, Uncuffed
73110-070	Size 7, Distal Extension, Uncuffed
73110-080	Size 8, Distal Extension, Uncuffed
73120-050	Size 5, Distal Extension, Cuffed
73120-060	Size 6, Distal Extension, Cuffed
73120-070	Size 7, Distal Extension, Cuffed
73120-080	Size 8, Distal Extension, Cuffed
77100-050	Size 5, XLT, Disposable Inner Cannula
77100-060	Size 6, XLT, Disposable Inner Cannula
77100-070	Size 7, XLT, Disposable Inner Cannula
77100-080	Size 8, XLT, Disposable Inner Cannula

The Company has received two reports in which the cannula separation was allegedly associated with two patient deaths. Those TracheoSoft XLT Tracheostomy Tubes

currently in use should be exchanged, when practical, with an alternative model at the discretion and judgment of the patient' s physician.

Institutions with affected product have received packages outlining the recall process. As of this date, 80 percent of those customers have responded to the recall action. The U.S. Food and Drug Administration (FDA) and officials in other affected countries have been apprised of this recall action.

This action does not affect any other model of Shiley tracheostomy products. We apologize for any disruption this action may cause physicians and their patients. Please be assured that Nellcor/Tyco Healthcare has taken appropriate steps to prevent recurrence of this problem and ensure patient safety.

Clinicians and patients with inquiries should contact our Technical Services Department at **1-800-635-5267, option 3**.

About Tyco Healthcare

Tyco Healthcare, a business segment of Tyco International Ltd., is a leading manufacturer, distributor and servicer of medical devices worldwide. Its broad portfolio includes disposable medical supplies, monitoring equipment, medical instruments and bulk analgesic pharmaceuticals, sold under such names as Auto Suture, Kendall, Mallinckrodt, Nellcor, Puritan Bennett, United States Surgical, Valleylab and others.

Updated August 9, 2004

smiths

Smiths Medical ASD, Inc.

Anesthesia and Safety Devices Division
5700 West 23rd Ave
Gary, IN 46406-2617 USA
Tel: 219-989-9150
Fax: 219-989-7435
www.smiths-medical.com

Special Offer for Shiley® XLT Users

Order a Bivona® ***Customized*** Fixed Neck Flange Hyperflex ™ tracheostomy tube from Smiths Medical for only $100 plus shipping.

Use our simple customized order template to:

- Select the desired tube O.D. size
- Select Aire-Cuf® or Cuffless
- Specify the tube length you require
- Select the Adult Straight Neck Flange
- Select the Hyperflex™ shaft style
- Select Standard Service
- Complete the lower left hand corner with clinician and patient information

There is a minimum quantity of two per patient.

If you have any questions please call 800-424-8662, prompt 6 or fax the template along with purchasing information to 219-989-7435.

smiths

Smiths Medical ASD, Inc.
Anesthesia and Safety Devices Division

O.D. Comparison Chart

Shiley® XLT Dimensions

Extension	Product Designation		Length (mm)	I.D. (mm)	O.D. (mm)
	Cuffed	Uncuffed			
Distal	73120-050	73110-050	90	5.0	9.6
Proximal	72120-050	72110-050	90	5.0	9.6
Distal	73120-060	73110-060	95	6.0	11.0
Proximal	72120-060	72110-060	95	6.0	11.0
Distal	73120-070	73110-070	100	7.0	12.3
Proximal	72120-070	72110-070	100	7.0	12.3
Distal	73120-080	73110-080	105	8.0	13.3
Proximal	72120-080	72110-080	105	8.0	13.3

Bivona® Hyperflex™ Dimensions

O.D. (mm)	I.D. (mm)
7.3	5.0
8.0	5.5
8.7	6.0
9.4	6.5
10.0	7.0
10.4	7.5
11.0	8.0
11.8	8.5
12.3	9.0
13.3	9.5

To order your customized Hyperflex tube, use our simple order template to:

1. Select TYPE SERVICE
2. Select NECK FLANGE TYPE- 'C'
3. Select SHAFT STYLE- 'HYPERFLEX'
4. Specify desired SHAFT: O.D. (refer to O.D. comparison chart)
   a. Note: Use O.D. since Shiley inner cannula reduces I.D. by 2 mm
5. Specify desired SHAFT LENGTH AT CENTER LINE (distal tube shaft length)
6. Select CUFF DISTANCE FROM TIP- 'STANDARD DISTANCE'
7. Select CUFF TYPE- 'AIRE-CUF' or 'UNCUFFED'
8. Ignore OPTIONAL choices
9. Completely fill out bottom left-hand portion of form
10. Fax the completed template along with a hard copy of the purchase order

CUSTOMIZED FIXED NECK FLANGE TRACHEOSTOMY TUBE TEMPLATE

SELECT TYPE SERVICE

- ☐ 3–4 WEEKS (STERILE)
- ☐ STANDARD SERVICE (NON STERILE)
- ☐ EXPRESS SERVICE (NON STERILE)
- ☐ SAME DAY SERVICE (NON STERILE)

NECK FLANGE TYPE:

A ☐

FIXED NECK FLANGE
AVAILABLE SIZES:
2.5 – 5.5mm

B ☐

FIXED NECK FLANGE
AVAILABLE SIZES:
2.5 – 9.5mm

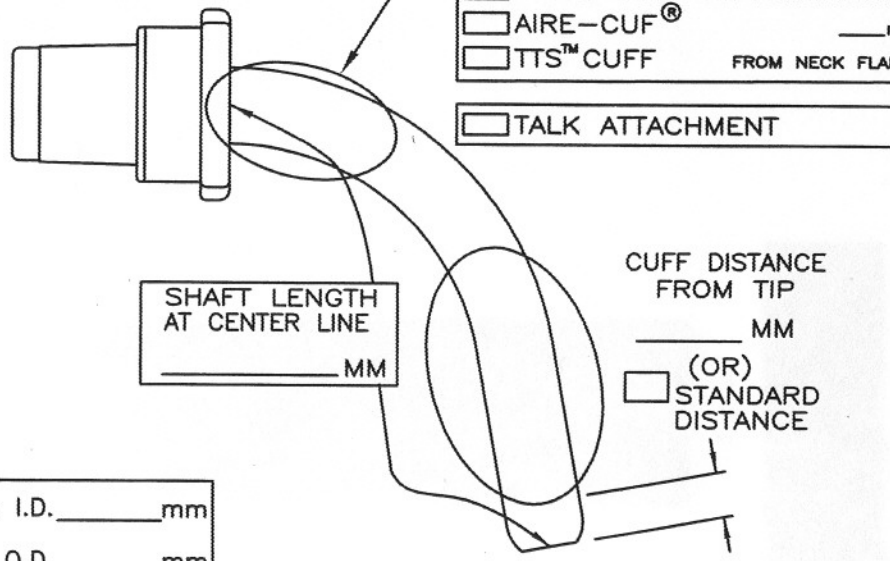
C ☐

FIXED NECK FLANGE
AVAILABLE SIZES:
2.5 – 9.5mm

(OPTIONAL)

- ☐ SOLID SILICONE
- ☐ FOME–CUF® CUFF POSITION FLUSH (OR) ____mm FROM NECK FLANGE
- ☐ AIRE–CUF®
- ☐ TTS™ CUFF

☐ TALK ATTACHMENT



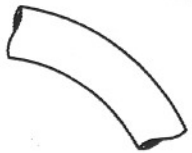
SHAFT LENGTH AT CENTER LINE
_____MM

CUFF DISTANCE FROM TIP
_____ MM
☐ (OR) STANDARD DISTANCE

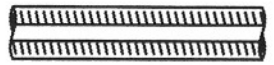
SHAFT: I.D._____mm
(OR) O.D._____mm

SHAFT STYLE:

STANDARD SILICONE ☐



☐ HYPERFLEX™

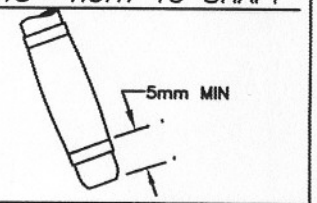


WIRE REINFORCED

CUFF TYPE(S):

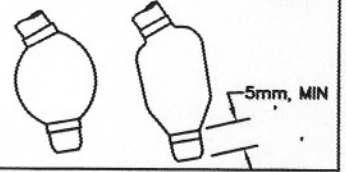
☐ UNCUFFED

☐ TTS™ TIGHT TO SHAFT

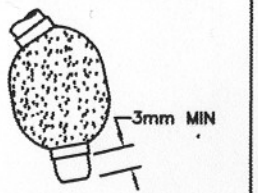


☐ AIRE–CUF®

PED. A/C ADULT A/C (MID–RANGE)



☐ FOME–CUF®



CLINICIAN:

CLINICIAN SIGNATURE: DATE:

CLINICIAN CREDENTIALS:

PATIENT/CLIENT NAME: FACILITY TYPE

FOR QUESTIONS CALL
1-800-258-5361

FOR COMPLETED TEMPLATES
FAX:(219)989-7435

BIVONA USE ONLY

BIVONA ENGRG. APPROVAL:

REORDER#

Bivona Medical Technologies

TMPLATE1 REV.M SR.03AfA

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
NOTE: PLEASE PRINT CLEARLY. BIVONA STAFF CANNOT MAKE ANY ALTERATIONS TO THE COMPLETED TEMPLATE.