

Smiths Medical Issues Urgent Device Recall Of Portex® Pediatric-Sized Tracheal Tubes

**Company Contact:
Robert Hanvik
651-628-7613**

FOR IMMEDIATE RELEASE – September 10, 2009 – ST. PAUL, Minn.- Smiths Medical announced that it is initiating a nationwide voluntary recall of Portex® Uncuffed Pediatric-Sized Tracheal Tubes (sizes 2.5, 3.0 and 3.5 mm) manufactured before September 2009.

Description of the Issue

A small number of tubes were manufactured with internal diameters slightly smaller than indicated on the labeling, which may create the potential for the clinician to experience difficulty passing through or withdrawing the suction catheter. The health consequences that may result from use of the defective device include the inability to remove secretions from the device and from the patient's airway, which may result in partial or complete obstruction of the airway and an inability to ventilate the patient. In addition, this defect may increase airway resistance and compromise the ability to ventilate the patient. There is a reasonable probability of serious injury and/or death. To date, the company has not received any reports of death or permanent injury related to this issue.

Recommended Action to be taken by the User in a Recall Notice sent directly to all customers, Smiths Medical is instructing them to return all unused Tracheal Tubes. This requires customers to take the following steps:

- Review inventory and segregate any unused product manufactured before September 2009 and within its expiration date.**
- Complete and return a Confirmation Form (included with the Recall Notice) by fax at 1-603-355-8157 to: Recall Administrator, Regulatory Affairs, Smiths Medical ASD, Inc.**

Following these steps, customers will be provided with specific directions regarding how to return unused product.

The products affected by this recall have the following Product Codes:

Product code Product description

100/105/025 Portex® Tracheal Tube, Oral/Nasal, Ivory 100/105/030 Portex® Tracheal Tube, Oral/Nasal, Ivory

100/105/035 Portex® Tracheal Tube, Oral/Nasal, Ivory

100/111/025 Portex® Tracheal Tube, Oral/Nasal, Siliconized 100/111/030 Portex® Tracheal Tube, Oral/Nasal, Siliconized

100/111/035 Portex® Tracheal Tube, Oral/Nasal, Siliconized

100/126/025 Portex® Tracheal Tube, Cut to Length, Oral, Siliconized 100/126/030 Portex® Tracheal Tube, Cut to Length, Oral, Siliconized

100/126/035 Portex® Tracheal Tube, Cut to Length, Oral, Siliconized
100/127/025 Portex® Tracheal Tube, Oral/Nasal, Murphy Eye, Clear 100/127/030
Portex® Tracheal Tube, Oral/Nasal, Murphy Eye, Clear
100/127/035 Portex® Tracheal Tube, Oral/Nasal, Murphy Eye, Clear 100/134/030
Portex® Polar Preformed Tracheal Tube, South Oral, Murphy Eye, Clear
100/134/035 Portex® Polar Preformed Tracheal Tube, South Oral, Murphy Eye,
Clear
100/141/025 Portex® Tracheal Tube, Oral/Nasal, Murphy Eye, Siliconized
100/141/030 Portex® Tracheal Tube, Oral/Nasal, Murphy Eye, Siliconized
100/141/035 Portex® Tracheal Tube, Oral/Nasal, Murphy Eye, Siliconized

If a Tracheal Tube is currently in use with a patient, there is no evidence to suggest that immediate removal of the Tracheal Tube is necessary. If suctioning of an Tracheal Tube currently in use is required, Smiths Medical recommends that customers refer to a company-supplied Guidance Chart for suction catheter sizes, available at www.smiths-medical.com.Clinicians who choose to use larger-than-recommended suction catheters should base this decision on sound clinical judgment and use caution, to assure the suction catheter readily passes through and can be readily withdrawn from the Tracheal Tube.

Recipients of the Recall Notice who have distributed Tracheal Tubes to other persons or facilities should promptly forward a copy of the Recall Notice to them. For questions regarding this Recall Notice, customers should contact:

**Charlotte Veysey
Regulatory Affairs
Smiths Medical ASD, Inc.
10 Bowman Drive
Keene, NH 03431 USA
Tel: 1-800-348-6064, prompt 4, ext 2273
Fax: 603-355-8157
E-mail:Charlotte.veysey@smiths-medical.com Customers should report any issues with the Portex® Tracheal Tubes to Smiths Medical's Technical Services Complaints Department at 1-866-216-8806.**