

## URGENT MEDICAL DEVICE NOTIFICATION

**BLUselect® Tracheostomy Tube Kits , BLUselect® Suctionaid® Tracheostomy Tube Kits, BLUgriggs® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with BLUselect® Tracheostomy Tube with or without Forceps, BLUperc® Dilation Procedural Tray with Single Stage Dilator Products, BLUperc® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with or without BLUselect® Tracheostomy Tube.**

13 June 2024:

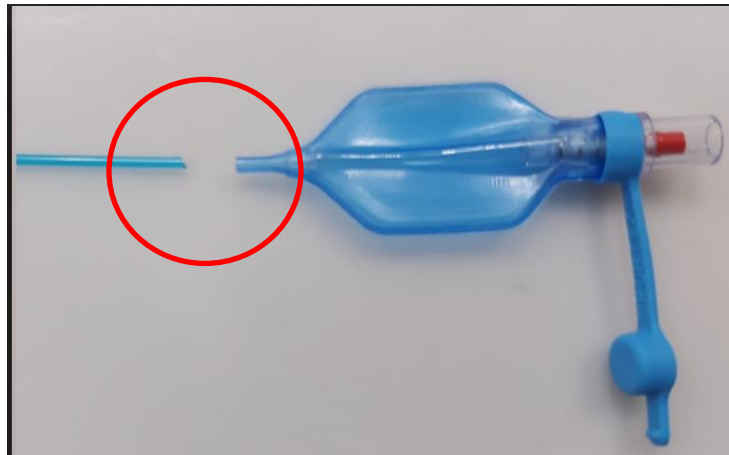
Dear Valued BLUSelect ® Customers:

- Director of Biomedical Engineering
- Director of Nursing
- Director of Respiratory Care

Smiths Medical, Inc. is issuing this Urgent Field Safety Notice to notify you of a potential defect with the following BLUselect®, BLUgriggs® and BLUperc® products listed in Attachment 1\_Affected Product. This letter details the issue and the required steps for you to complete.

**Issue:**

Smiths Medical has identified the potential for a disconnection of the pilot balloon from the tracheostomy inflation line within specific lots of the BLUselect®, BLUgriggs® and BLUperc® products because of a manufacturing defect. See the photo example of the issue below.



**Potential Risk:**

If the pilot balloon used to inflate the tracheostomy cuff becomes detached from the inflation line, the cuff pressure may not be maintained which can lead to inadequate ventilation of, and increased risk of aspiration to the patient. To date, Smiths Medical has received twelve (13) reports of serious injury and zero (0) deaths associated with this issue.

**Affected Product:**

See the Affected Product Codes Listed in the Attachment 1\_Affected Product.

**Smiths Medical Action:**

Smiths Medical is sending this notification to all BLUSelect®, BLUgriggs® and BLUperc® customers who received product(s) from Smiths Medical listed in the Attachment 1\_Affected Product. Smiths Medical will provide replacement product(s) and/or credit is available for affected customers. Please contact your local representative with your certificate of destruction to coordinate the replacement/credit.

**Customer Required Actions:**

When using the device, all instructions, including warning and cautions contained in the Instructions for Use documentation must be followed with heightened awareness. Please complete the following actions listed below:

1. Check all inventory locations within your institution for the specific lots of the affected product codes listed in the notification and discontinue use. Discard all affected products following your institution’s process for discarding. If discarding is not immediately possible at your facility, then the product should be quarantined until disposal.
2. Share this notification with all potential users of the devices to ensure they are aware of this notification and proposed mitigations. If the devices are used at another location, please ensure this communication is delivered there.
3. Complete and return the attached Customer Response Form to [smithsmedical8551@sedgwick.com](mailto:smithsmedical8551@sedgwick.com) ***within 10 days of receipt*** to acknowledge your understanding of this notification. Please contact your local representative for replacement product and/or a credit.
4. DISTRIBUTORS: If you have distributed potentially affected products to your customers, please immediately forward this notice to them. Request that they complete the response form and return it to [smithsmedical8551@sedgwick.com](mailto:smithsmedical8551@sedgwick.com)

If you have any questions regarding product replacement and/or credit, please contact Smiths Medical Customer Service below:

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	<a href="mailto:globalcomplaints@icumed.com">globalcomplaints@icumed.com</a> 1-(866)-216-8806	To report adverse events or product complaints
Customer Service	<a href="mailto:Customerservice@icumed.com">Customerservice@icumed.com</a> 1-(800)-0258-5361	Questions about product replacement and/or credit.

This notification is being performed with the knowledge of regulatory authorities, including the US Food and Drug Administration (FDA).

If you wish to contact the FDA regarding any adverse events or quality problems associated with this notice, use the following contact information.

- [www.fda.gov/medwatch](http://www.fda.gov/medwatch)
- 1-(888)-INFO-FDA

Smiths Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,



Andy Mathein  
Vice President of Quality

**Enclosures:**

- Customer Response Form
- Attachment 1\_Affected Product