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URGENT: FIELD SAFETY NOTICE

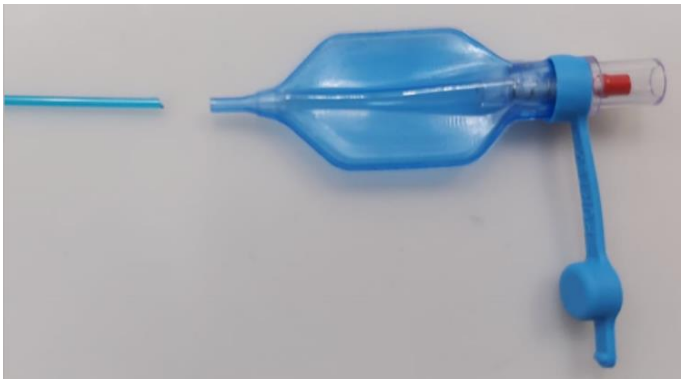
BLUselect® Tracheostomy Tube Kits , BLUselect® Suctionaid® Tracheostomy Tube Kits, BLUgriggs® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with BLUselect® Tracheostomy Tube with or without Forceps, BLUperc® Dilation Procedural Tray with Single Stage Dilator Products, BLUperc® Percutaneous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

15th August 2024

Dear Valued BLUSelect® Customers,

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 thirteen (13) reports of serious injury and zero (0) deaths associated with this issue.

Affected Product
Please see the affected item and lot numbers in Attachment 1_Affected Product List and also product distribution date range.

Smiths Medical Actions:
Smiths Medical is sending this notification to all BLUSelect®, BLUgriggs® and BLUperc® customers who received products from Smiths Medical listed in *Attachment 1_Affected Product*. Smiths Medical will provide credit to affected customers upon receipt of a completed response form to certify product destruction.

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 affected catalog numbers and lot numbers 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 device 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 EMEA-FSN@icumed.com within 10 days of receipt to acknowledge your understanding of this notification.

4. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them and request that they complete the response form and return it to **YOU**. Then the **DISTRIBUTOR** must complete a SINGLE form with the required details and return to EMEA-FSN@icumed.com

For further inquiries, please contact Smiths Medical using the following information:

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@icumed.com	To report adverse events or product complaints
Customer Service	https://www.icumed.com/about-us/contact-us	Questions about product replacement and/or credit.

Your country regulatory agency has been notified of this action

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,

[redacted]

Andy Mathein
Vice President of Quality

Enclosures:

- Customer Response Form (See Below)
- Affected Product List (Attachment 1)

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URGENT: FIELD SAFETY NOTICE – RESPONSE FORM

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

15th August 2024

Check your inventory and complete the information below, even if you do not have the affected product. *Failure to complete all sections of this page may result in improper, delayed or denied credit.*

Please return the completed form to EMEA-FSN@icumed.com, If you have questions about this form please contact EMEA-FSN@icumed.com or your local sales representative.

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

Please select one:

☐ I have **NO** affected products (complete and return this form to the e-mail address above)

☐ **YES**, I have affected products, I have notified users in my facility and I have followed the instructions provided to me and destroyed all affected items (see table below)

If you have affected product on hand, please complete table 1 below:

TABLE 1

Item / SKU Number	Lot Number	Quantity in inventory (Eaches)	Quantity Destroyed (Eaches)	Date of Destruction

If you have distributed the product further, please complete table 2 below with collated information received from your customers and respond to ICU Medical with the overall information.

TABLE 2

Item / SKU Number	Lot Number	Quantity destroyed locally (Eaches)	Date of Destruction

Adverse events and complaints associated with the use of this product should be reported and emailed to Smiths Medical's Global Complaint Management Department at globalcomplaints@icumed.com.

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ADDITIONAL AFFECTED PRODUCT DESTROYED

Item / SKU Number	Lot Number	Quantity in inventory (Eaches)	Quantity Destroyed (Eaches)	Date of Destruction

Affected items below were distributed in Switzerland between Jul 2021 and Feb 2024

SKU/List/Model Number	Product Description	Lot Number
101/541/070	BLUgriggs® Percutaneous Dilation Procedural Kit with forceps and 7.0mm BLUselect® trach tube	3913366
101/541/080	BLUgriggs® Percutaneous Dilation Procedural Kit with forceps and 8.0mm BLUselect® trach tube	4312324
101/561/080	BLUperc Percutaneous Dilation Procedural Kit with Single Stage Dilator and 8.0 mm BLUselect trach tube	4348886
101/561/080	BLUperc Percutaneous Dilation Procedural Kit with Single Stage Dilator and 8.0 mm BLUselect trach tube	4382035
101/561/080	BLUperc Percutaneous Dilation Procedural Kit with Single Stage Dilator and 8.0 mm BLUselect trach tube	4382038
101/561/080	BLUperc Percutaneous Dilation Procedural Kit with Single Stage Dilator and 8.0 mm BLUselect trach tube	4408626
101/561/090	BLUperc Percutaneous Dilation Procedural Kit with Single Stage Dilator and 9.0 mm BLUselect trach tube	4415811
101/563/080	BLUperc® Percutaneous Dilation Procedural Kit with 8.0mm BLUselect® Suctionaid® Trach Tube	4348857
101/563/080	BLUperc® Percutaneous Dilation Procedural Kit with 8.0mm BLUselect® Suctionaid® Trach Tube	4348860
101/563/080	BLUperc® Percutaneous Dilation Procedural Kit with 8.0mm BLUselect® Suctionaid® Trach Tube	4385043
101/800/060CZ	BLUSELECT 6.0, CUFFED, NON-FEN	4382002
101/800/070CZ	BLUSELECT 7.0, CUFFED, NON-FEN	4305944
101/800/075CZ	BLUSELECT 7.5, CUFFED, NON-FEN	4348898
101/800/075CZ	BLUSELECT 7.5, CUFFED, NON-FEN	4348899
101/800/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4305935
101/800/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4305936
101/800/085CZ	BLUSELECT 8.5, CUFFED, NON-FEN	4348861
101/800/090CZ	BLUSELECT 9.0, CUFFED, NON-FEN	4310439
101/800/090CZ	BLUSELECT 9.0, CUFFED, NON-FEN	4376612
101/800/100CZ	BLUSELECT 10.0, CUFFED, NON-FEN	4386600
101/800/100CZ	BLUSELECT 10.0, CUFFED, NON-FEN	4413606
101/810/070CZ	BLUSELECT 7.0, CUFFED, NON-FEN	4285856
101/810/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4230143
101/810/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4306016
101/810/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4312272
101/810/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4381980
101/810/085CZ	BLUSELECT 8.5, CUFFED, NON-FEN	4306011
101/810/090CZ	BLUSELECT 9.0, CUFFED, NON-FEN	4243117
101/810/090CZ	BLUSELECT 9.0, CUFFED, NON-FEN	4306027
101/810/090CZ	BLUSELECT 9.0, CUFFED, NON-FEN	4403367
101/810/100CZ	BLUSELECT 10.0, CUFFED, NON-FEN	4312263
101/812/070CZ	BLUSELECT 7.0, CUFFED, FEN	4242910
101/812/075CZ	BLUSELECT 7.5, CUFFED, FEN	4381979
101/812/075CZ	BLUSELECT 7.5, CUFFED, FEN	4413594
101/812/085CZ	BLUSELECT 8.5, CUFFED, FEN	4382043
101/812/090CZ	BLUSELECT 9.0, CUFFED, FEN	4243118
101/812/100CZ	BLUSELECT 10.0, CUFFED, FEN	4381995
101/812/100CZ	BLUSELECT 10.0, CUFFED, FEN	4423838
101/860/075CZ	BLUSELECT 7.5, SUCTIONAID, CUFFED, NON-FEN	4386514
101/860/080CZ	BLUSELECT 8.0, SUCTIONAID, CUFFED, NON-FEN	4386575
101/860/090CZ	BLUSELECT 9.0, SUCTIONAID, CUFFED, NON-FEN	4310533
101/860/100CZ	BLUSELECT 10.0, SUCTIONAID, CUFFED, NON-FEN	4412135
101/870/070CZ	BLUSELECT 7.0, SUCTIONAID, CUFFED, NON-FEN	4283719
101/870/075CZ	BLUSELECT 7.5, SUCTIONAID, CUFFED, NON-FEN	4382010
101/870/080CZ	BLUSELECT 8.0, SUCTIONAID, CUFFED, NON-FEN	4319800
101/870/085CZ	BLUSELECT 8.5, SUCTIONAID, CUFFED, NON-FEN	4376585
101/870/090CZ	BLUSELECT 9.0, SUCTIONAID, CUFFED, NON-FEN	4303381
101/870/100CZ	BLUSELECT 10.0, SUCTIONAID, CUFFED, NON-FEN	4306010
101/893/070	BLUgriggs® Percutaneous Dilation Procedural Kit with 7.0mm BLUselect® Suctionaid® Trach Tube, no forceps	4005285