

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

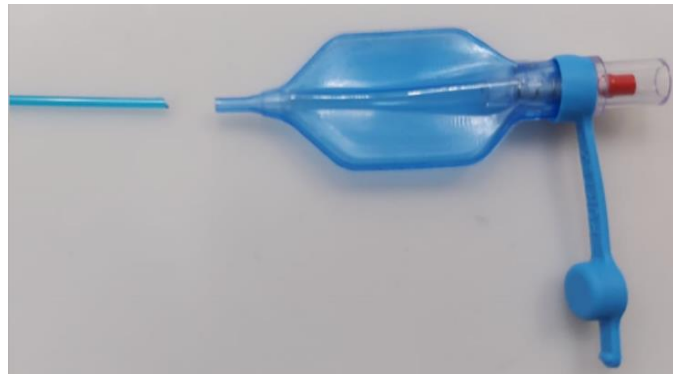
15th August 2024

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 on pages 5-7. 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 on pages 5-7 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 on pages 5-7. 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,



Andy Mathein
Vice President of Quality

Enclosures:

- Customer Response Form (See Below)
- Affected Product List (see pages 5-7)

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.

ADDITIONAL AFFECTED PRODUCT DESTROYED

[illegible]

Affected items below were distributed in Denmark between May 2020 and Mar 2024

SKU/List/Model Number	Product Description	Lot Number
101/543/070	BLUgriggs® Percutaneous Dilation Procedural Kit with 7.0mm BLUselect® Trach Tube, no forceps	3887541
101/561/080	BLUperc Percutaneous Dilation Procedural Kit with Single Stage Dilator and 8.0 mm BLUselect trach tube	4249230
101/561/080	BLUperc Percutaneous Dilation Procedural Kit with Single Stage Dilator and 8.0 mm BLUselect trach tube	4382040
101/561/080	BLUperc Percutaneous Dilation Procedural Kit with Single Stage Dilator and 8.0 mm BLUselect trach tube	4386516
101/561/080	BLUperc Percutaneous Dilation Procedural Kit with Single Stage Dilator and 8.0 mm BLUselect trach tube	4386518
101/561/080	BLUperc Percutaneous Dilation Procedural Kit with Single Stage Dilator and 8.0 mm BLUselect trach tube	4396543
101/561/090	BLUperc Percutaneous Dilation Procedural Kit with Single Stage Dilator and 9.0 mm BLUselect trach tube	4310485
101/561/090	BLUperc Percutaneous Dilation Procedural Kit with Single Stage Dilator and 9.0 mm BLUselect trach tube	4382034
101/561/090	BLUperc Percutaneous Dilation Procedural Kit with Single Stage Dilator and 9.0 mm BLUselect trach tube	4397559
101/563/070	BLUperc® Percutaneous Dilation Procedural Kit with 7.0mm BLUselect® Suctionaid® Trach Tube	4281148
101/563/080	BLUperc® Percutaneous Dilation Procedural Kit with 8.0mm BLUselect® Suctionaid® Trach Tube	4348845
101/563/080	BLUperc® Percutaneous Dilation Procedural Kit with 8.0mm BLUselect® Suctionaid® Trach Tube	4348848
101/563/080	BLUperc® Percutaneous Dilation Procedural Kit with 8.0mm BLUselect® Suctionaid® Trach Tube	4396537
101/563/090	BLUperc® Percutaneous Dilation Procedural Kit with 9.0mm BLUselect® Suctionaid® Trach Tube	4348865
101/800/060CZ	BLUSELECT 6.0, CUFFED, NON-FEN	4106716
101/800/070CZ	BLUSELECT 7.0, CUFFED, NON-FEN	4152440
101/800/070CZ	BLUSELECT 7.0, CUFFED, NON-FEN	4238237
101/800/070CZ	BLUSELECT 7.0, CUFFED, NON-FEN	4249341
101/800/070CZ	BLUSELECT 7.0, CUFFED, NON-FEN	4305944
101/800/070CZ	BLUSELECT 7.0, CUFFED, NON-FEN	4305947
101/800/070CZ	BLUSELECT 7.0, CUFFED, NON-FEN	4368641
101/800/075CZ	BLUSELECT 7.5, CUFFED, NON-FEN	4238234
101/800/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4138225
101/800/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4232686
101/800/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4270931
101/800/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4305933
101/800/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4305934

SKU/List/Model Number	Product Description	Lot Number
101/800/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4305935
101/800/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4305936
101/800/090CZ	BLUSELECT 9.0, CUFFED, NON-FEN	4310439
101/802/080CZ	BLUSELECT 8.0, CUFFED, FEN	3951185
101/810/060CZ	BLUSELECT 6.0, CUFFED, NON-FEN	4106722
101/810/060CZ	BLUSELECT 6.0, CUFFED, NON-FEN	4268673
101/810/070CZ	BLUSELECT 7.0, CUFFED, NON-FEN	3887478
101/810/070CZ	BLUSELECT 7.0, CUFFED, NON-FEN	4106813
101/810/070CZ	BLUSELECT 7.0, CUFFED, NON-FEN	4254571
101/810/070CZ	BLUSELECT 7.0, CUFFED, NON-FEN	4285856
101/810/075CZ	BLUSELECT 7.5, CUFFED, NON-FEN	4281153
101/810/075CZ	BLUSELECT 7.5, CUFFED, NON-FEN	4381994
101/810/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	3887481
101/810/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4230143
101/810/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4285773
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
101/810/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4387365
101/810/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4403461
101/810/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4415817
101/810/080CZ	BLUSELECT 8.0, CUFFED, NON-FEN	4423832
101/810/090CZ	BLUSELECT 9.0, CUFFED, NON-FEN	4106736
101/810/090CZ	BLUSELECT 9.0, CUFFED, NON-FEN	4173266
101/810/090CZ	BLUSELECT 9.0, CUFFED, NON-FEN	4243117
101/810/090CZ	BLUSELECT 9.0, CUFFED, NON-FEN	4306027
101/812/060CZ	BLUSELECT 6.0, CUFFED, FEN	3976752
101/812/060CZ	BLUSELECT 6.0, CUFFED, FEN	4106752
101/812/060CZ	BLUSELECT 6.0, CUFFED, FEN	4294444
101/812/070CZ	BLUSELECT 7.0, CUFFED, FEN	3968279
101/812/070CZ	BLUSELECT 7.0, CUFFED, FEN	4106754
101/812/070CZ	BLUSELECT 7.0, CUFFED, FEN	4242910
101/812/080CZ	BLUSELECT 8.0, CUFFED, FEN	4385065
101/812/100CZ	BLUSELECT 10.0, CUFFED, FEN	4064797
101/860/060CZ	BLUSELECT 6.0, SUCTIONAID, CUFFED, NON-FEN	4242923
101/860/070CZ	BLUSELECT 7.0, SUCTIONAID, CUFFED, NON-FEN	4234709
101/860/075CZ	BLUSELECT 7.5, SUCTIONAID, CUFFED, NON-FEN	3909675
101/860/075CZ	BLUSELECT 7.5, SUCTIONAID, CUFFED, NON-FEN	4387362
101/860/080CZ	BLUSELECT 8.0, SUCTIONAID, CUFFED, NON-FEN	4388728

SKU/List/Model Number	Product Description	Lot Number
101/870/060CZ	BLUSELECT 6.0, SUCTIONAID, CUFFED, NON-FEN	4106745
101/870/060CZ	BLUSELECT 6.0, SUCTIONAID, CUFFED, NON-FEN	4217882
101/870/070CZ	BLUSELECT 7.0, SUCTIONAID, CUFFED, NON-FEN	3968404
101/870/070CZ	BLUSELECT 7.0, SUCTIONAID, CUFFED, NON-FEN	4138214
101/870/070CZ	BLUSELECT 7.0, SUCTIONAID, CUFFED, NON-FEN	4178001
101/870/070CZ	BLUSELECT 7.0, SUCTIONAID, CUFFED, NON-FEN	4217826
101/870/070CZ	BLUSELECT 7.0, SUCTIONAID, CUFFED, NON-FEN	4249291
101/870/070CZ	BLUSELECT 7.0, SUCTIONAID, CUFFED, NON-FEN	4256336
101/870/070CZ	BLUSELECT 7.0, SUCTIONAID, CUFFED, NON-FEN	4283719
101/870/070CZ	BLUSELECT 7.0, SUCTIONAID, CUFFED, NON-FEN	4291171
101/870/075CZ	BLUSELECT 7.5, SUCTIONAID, CUFFED, NON-FEN	4061022
101/870/075CZ	BLUSELECT 7.5, SUCTIONAID, CUFFED, NON-FEN	4238185
101/870/075CZ	BLUSELECT 7.5, SUCTIONAID, CUFFED, NON-FEN	4249236
101/870/075CZ	BLUSELECT 7.5, SUCTIONAID, CUFFED, NON-FEN	4270941
101/870/075CZ	BLUSELECT 7.5, SUCTIONAID, CUFFED, NON-FEN	4276631
101/870/075CZ	BLUSELECT 7.5, SUCTIONAID, CUFFED, NON-FEN	4382010
101/870/080CZ	BLUSELECT 8.0, SUCTIONAID, CUFFED, NON-FEN	4138056
101/870/080CZ	BLUSELECT 8.0, SUCTIONAID, CUFFED, NON-FEN	4163106
101/870/080CZ	BLUSELECT 8.0, SUCTIONAID, CUFFED, NON-FEN	4208997
101/870/080CZ	BLUSELECT 8.0, SUCTIONAID, CUFFED, NON-FEN	4238168
101/870/080CZ	BLUSELECT 8.0, SUCTIONAID, CUFFED, NON-FEN	4254564
101/870/080CZ	BLUSELECT 8.0, SUCTIONAID, CUFFED, NON-FEN	4303380
101/870/080CZ	BLUSELECT 8.0, SUCTIONAID, CUFFED, NON-FEN	4310523
101/870/080CZ	BLUSELECT 8.0, SUCTIONAID, CUFFED, NON-FEN	4312285
101/870/080CZ	BLUSELECT 8.0, SUCTIONAID, CUFFED, NON-FEN	4317581
101/870/080CZ	BLUSELECT 8.0, SUCTIONAID, CUFFED, NON-FEN	4319800
101/870/080CZ	BLUSELECT 8.0, SUCTIONAID, CUFFED, NON-FEN	4368642
101/870/080CZ	BLUSELECT 8.0, SUCTIONAID, CUFFED, NON-FEN	4390747
101/870/085CZ	BLUSELECT 8.5, SUCTIONAID, CUFFED, NON-FEN	4067915
101/870/085CZ	BLUSELECT 8.5, SUCTIONAID, CUFFED, NON-FEN	4085217
101/870/085CZ	BLUSELECT 8.5, SUCTIONAID, CUFFED, NON-FEN	4212070
101/870/085CZ	BLUSELECT 8.5, SUCTIONAID, CUFFED, NON-FEN	4249238
101/870/085CZ	BLUSELECT 8.5, SUCTIONAID, CUFFED, NON-FEN	4376585
101/870/090CZ	BLUSELECT 9.0, SUCTIONAID, CUFFED, NON-FEN	4178002
101/870/090CZ	BLUSELECT 9.0, SUCTIONAID, CUFFED, NON-FEN	4285763
101/870/090CZ	BLUSELECT 9.0, SUCTIONAID, CUFFED, NON-FEN	4285764
101/870/090CZ	BLUSELECT 9.0, SUCTIONAID, CUFFED, NON-FEN	4303381
101/870/090CZ	BLUSELECT 9.0, SUCTIONAID, CUFFED, NON-FEN	4387367