smiths medical
bringing technology to life

6000 Nathan Lane N.
Minneapolis, MN 55442

Rcvd 6/18/24

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.

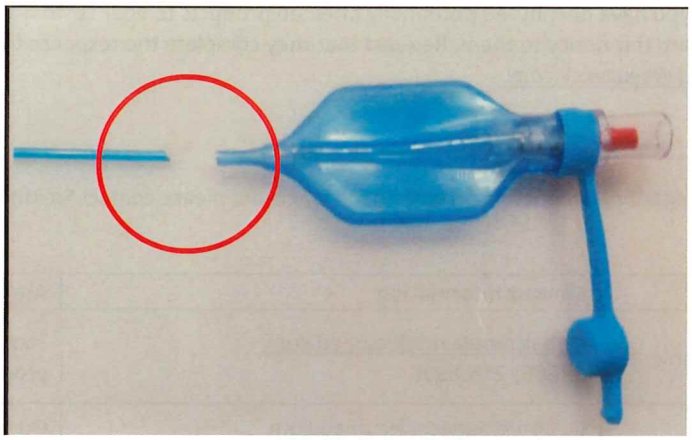
13 June 2024:

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.

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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 ***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

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	globalcomplaints@icumed.com 1-(866)-216-8806	To report adverse events or product complaints
Customer Service	Customerservice@icumed.com 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
- 1-(888)-INFO-FDA

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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

101/817/080 BLUSELECT 8.0, CUFFED, FEN, W/WEDGE AND DECAN CAP

3933831 3962715 4062550 4068195 4230801 4294937

101/596/ 080 BLUperc® Percutaneous Dilation Procedural Tray with 8.0mm BLUselect® Suctionaid® Trach Tube

3898770 3979602 4008832 3979615 4060531 4036527 4069871 4119536
4101970 4146207 4110837 4131437 4179935 4246523 4268459 4241328
4252236 4256036 4307794 4415596 4436549

101/595/090 BLUperc® Percutaneous Dilation Procedural Tray with 9.0mm BLUselect®

3898768 3944042 3950056 4008834 3987809 4036473 4036503 4008836
4060529 4098459 4168614 4110836 4177105 4183504 4291330 4294002
4324771 4330618 4263406 4265778 4344183 4423957

101/595/070 BLUperc® Percutaneous Dilation Procedural Tray with 7.0mm BLUselect®

3898766 4002180 4008828 4032081 4060523 4086681 4168564 4256056
4234424 4242669 4280697 4293992 4324235 4352941 4333064 4415609
4423960 4415588

101/892/080 BLUgriggs® Percutaneous Dilation Procedural Tray with forceps and

3943993 4165114 4226926

101/892/090 BLUgriggs® Percutaneous Dilation Procedural Tray with forceps and

39944020 4194294

101/892/070 BLUgriggs® Percutaneous Dilation Procedural Tray with forceps and

3950087

101/596/070 BLUperc® Percutaneous Dilation Procedural Tray with 7.0mm BLUselect®

3944058 3967805 4008830 4060560 4098464 4116821 4123503 4134674
4240514 4241327 4285358 4275910 4263399 4415589 4423966 4428303

101/596/090 BLUperc® Percutaneous Dilation Procedural Tray with 9.0mm BLUselect®

3950088 3944050 4008815 4032080 4060533 4119537 4098449 4101971
4123504 4261158 4280743 4285393 4270589 4263403 4301196 4319347
4423968 4326871 4436550 4119537 4098449 4101971 4123504 4261158
4280743 4285393 4270589 4263403 4301196 4319347 4423968 4326871
4436550 4447674

101/540/080 BLUgriggs Percutaneous Dilation Procedural Tray with forceps and

3943992 4258998

101/815/075 BLUSELECT 7.5, CUFFED, NON-FEN, W/WEDGE

101/815/080 BLUSELECT 8.0, CUFFED, NON-FEN, W/WEDGE, 1/EA					
3905015	3940109	3942887	3965245	3965245	4021055
4058347	4029161	4100474	4118284	4187081	4169838
4190342	4202303	4204266	4206466	4192320	4204265
4274832	4209172	4294948	4336668	4336649	4336646

101/815/070 BLUSELECT 7.0, CUFFED, NON-FEN, W/WEDGE, 1/EA							
3905154	3949269	3965244	4039241	4032511	4091935	4115649	4121851
4187085	4131921	4187074	4196637	4219471	4214909	4220399	4223153
4277368	4260338	4306727	4306851	4292624	4294949	4306852	4332676
4332678	4332684	4336640	4369413				

101/595/080 BLUperc Percutaneous Dilation Procedural Tray with Single Stage Dilator							
3898767	3950078	3950077	3987811	3991671	4008820	4008820	4032079
4032077	4060526	4072732	4086680	4098486	4110835	4131412	4148995
4128476	4163147	4179977	4265777	4256035	4272986	4283836	4296804
4324236	4326879	4330616	4339190	4259012	4341351	4425478	

101/875/080 BLUSELECT 8.0, SUCTIONAID, CUFFED, NON-FEN, W/WEDGE, 1/EA							
3905060	4038638	4071393	4091522	4106655	4083162	4088887	4124771
4220404	4187079	4187084	4202304	4279527	4294941	4375952	

101/817/060 BLUSELECT 6.0, CUFFED, FEN, W/WEDGE AND DECAN CAP, 1/EA		
3905152	4106973	4174794

101/815/100 BLUSELECT 10.0, CUFFED, NON-FEN, W/WEDGE							
3933697	4029154	4148895	4112822	4161638	4021081	4187096	4169842
4192321	4284378	4206174					

101/815/060 BLUSELECT 6.0, CUFFED, NON-FEN, W/WEDGE							
3933722	3940999	3949223	4014730	4035539	4021067	4118283	4121883
4159150	4164109	4187097	4166710	4177295	4174793	4177293	4369411
4369412	4269270	4380967					

101/817/100 BLUSELECT 10.0, CUFFED, FEN, W/WEDGE AND DECAN CAP	
3933799	4187080

101/815/060 BLUSELECT 6.0, CUFFED, NON-FEN, W/WEDGE		
3905152	4106973	4174794

101/815/090 BLUSELECT 9.0, CUFFED, NON-FEN, W/WEDGE							
3933809	3949146	4011017	4026491	4076707	4021088	4159151	4169841
4185327	4178241	4200171	4169840	4204267	4200170	4279525	4212316
4216557	4260339	4294947	4334212	4336647	4336650		

3956297 4071378 4126686 4174782 4294945 4332682 4362485 4414625
4428012

101/815/075 BLUSELECT 8.5, SUCTIONAID, CUFFED, NON-FEN, W/WEDGE

3956339 4119879 4106981 4202297 4187077 4216554

101/815/085 BLUSELECT 8.5, CUFFED, NON-FEN, W/WEDGE

3956296 4090264 4071392 4209173 4332683 4369414

101/875/070 BLUSELECT 7.0, SUCTIONAID, CUFFED, NON-FEN, W/WEDGE

3965241 4040743 3997476 4040744 4040748 4083147 4090267 4106657
4106653 4130528 4219470 4244045 4244044

101/875/060 BLUSELECT 6.0, SUCTIONAID, CUFFED, NON-FEN, W/WEDGE

3973580 3994206 4077390 4077409 4106652 4097405 4121852 4174792
4185328 4228918 4294942 4306861

101/561/080 BLUperc Percutaneous Dilation Procedural Kit with Single Stage Dilator

3887536 3906566 3906567 3906568 4288974 4285877 4291189 4348879
4348885 4308334 4348883 4348877 4386518

101/561/070 BLUperc Percutaneous Dilation Procedural Kit with Single Stage Dilator

3928959 4005346 4217858 4234862 4266405 4348810

101/875/075 BLUSELECT 7.5, SUCTIONAID, CUFFED, NON-FEN, W/WEDGE

3965238, 4106984, 4230803 4318743, 4294936,

101/875/100 BLUSELECT 10.0, SUCTIONAID, CUFFED, NON-FEN, W/WEDGE

3905062

101/875/090 BLUSELECT 9.0, SUCTIONAID, CUFFED, NON-FEN, W/WEDGE

4034431 4068186 4067217 4106999 4106650 4115631 4118290 4187086
4206467 4216550 4220407

101/817/090 BLUSELECT 9.0, CUFFED, FEN, W/WEDGE AND DECAN CAP

3941008 4076692 4071380 4106651

101/817/070 BLUSELECT 7.0, CUFFED, FEN, W/WEDGE AND DECAN CAP

3986585 3956189 4107000 4118288 4187078 4130527 4208001

101/563/070 BLUperc® Percutaneous Dilation Procedural Kit with 7.0mm BLUselect®

3948836 4017238 4054722 4054801 4054723 4165746 4234758

101/561/090 BLUperc Percutaneous Dilation Procedural Kit with Single Stage Dilator

3928993 3976736 4205592 4234863 4285761 4281078 4242949

X

101/540/090 BLUgriggs Percutaneous Dilation Procedural Tray with forceps and

4309778

X

101/563/080 BLUperc® Percutaneous Dilation Procedural Kit with 8.0mm BLUselect®

4348839

X