

URGENT MEDICAL DEVICE CORRECTION

Intubation ORAL/NASAL Endotracheal Tube

13 February 2025:

Dear Valued Customers:
Director of Respiratory
Director of Nursing
Director of Risk Management

Smiths Medical is issuing this letter to notify you of an issue with the Intubation ORAL/NASAL Endotracheal Tube. The following information details the issue and the required steps for you to perform.

Issue:

Smiths Medical became aware that certain sizes of Intubation ORAL/NASAL Endotracheal Tube products may have a smaller diameter than expected.

Potential Risk:

If the diameter of the device is smaller than expected, it may potentially result in inadequate ventilation to the patient, post-insertion of the endotracheal tube.

In such situations, the patient may experience hypoxia, underdose, and/or cardiopulmonary collapse.

To date, Smiths Medical has received eight (8) reports of serious injury that are potentially related to this issue.

Table 1: Affected Products(s)

The affected products are listed in the table below.

Affected Product Name	Affected Product	UDI
TRACHEAL TUBE SILICONISED ORAL/NASAL UNCUFFED 2.5MM 10/BX	100/111/025	15019315018848
TRACHEAL TUBE M/EYE UNCUFFED SILICONISED ORAL/NASAL 3.5MM 10/BX	100/141/035	15019315019043
TRACHEAL TUBE MURPHY EYE UNCUFFED SILICONISED ORAL/NASAL 3.0MM 10/BX	100/127/030	15019315019814
TRACHEAL TUBE MURPHY EYE UNCUFFED SILICONISED ORAL/NASAL 3.0MM 10/BX	100/141/030	15019315019036
TRACHEAL TUBE IVORY UNCUFFED ORAL/NASAL 2.5MM 10/BX	100/105/025	15019315018633
TRACHEAL TUBE MURPHY EYE UNCUFFED SILICONISED ORAL/NASAL 2.5MM 10/BX	100/127/025	15019315019807

TRACHEAL TUBE SILICONIZED CUT-TO-LENGTH. ORAL 2.5MM 10/BX	100/126/025	15019315056758
TRACHEAL TUBE MURPHY EYE UNCUFFED SILICONISED ORAL/NASAL 2.5MM 10/BX	100/141/025	15019315019029
TRACHEAL TUBE SILICONISED ORAL/NASAL UNCUFFED 2.0MM 10/BX	100/111/020	15019315018831
TRACHEAL TUBE SILICONISED ORAL/NASAL UNCUFFED 3.0MM 10/BX	100/111/030	15019315018855
TRACHEAL TUBE SILICONIZED CUT-TO-LENGTH. ORAL 3.0MM 10/BX	100/126/030	15019315056765
TRACHEAL TUBE SILICONIZED CUT-TO-LENGTH. ORAL 3.5MM 10/BX	100/126/035	15019315056772
TRACHEAL TUBE IVORY UNCUFFED ORAL/NASAL 3.5MM 10/BX	100/105/035	15019315018657
TRACHEAL TUBE MURPHY EYE UNCUFFED SILICONISED ORAL/NASAL 3.5MM 10/BX	100/127/035	15019315019821
TRACHEAL TUBE SILICONISED ORAL/NASAL UNCUFFED 3.5MM 10/BX	100/111/035	15019315018862
TRACHEAL TUBE IVORY UNCUFFED ORAL/NASAL 3.0MM 10/BX	100/105/030	15019315018640

Please refer to Appendix A for affected product lot numbers.

Customer Required Actions

- 1) Check all inventory locations within your institution for the affected products listed in the notification and discontinue use. Destroy all affected products following your institution’s process for destruction. If destroying 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. 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 smithsmedical6767@sedgwick.com within 10 days of receipt to acknowledge your understanding of this notification.

DISTRIBUTORS: If you have distributed affected products to your customers, please immediately forward this notice to them. Request that they complete the response form and return it to smithsmedical6767@sedgwick.com.

For further inquiries, please contact Smiths Medical using the information provided 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 1-800-258-5361	Questions about product for credit
Field Action Processing	smithsmedical6767@sedgwick.com 1-877-877-0317	Questions about this communication

General Information:

The U.S. Food and Drug Administration (FDA) has been notified of this action.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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,



Andrew Mathein
Vice President of Quality

Enclosures:

Customer Response Form
Frequently Asked Questions

Appendix A

Affected Products	Lots							
100/105/025	3911500	4110012	4308451	3986480	4222894	4255323	3954958	4159071
	3927026	4135634	4337267	4014665	4284465	4062708	4345413	
100/105/030	3880748	4121698	3990354	3904782	4282245	4354054	6025898	6054524
	3891668	4214842	4062709	3955939	4264607	6001192	4337268	6018580
100/105/035	3874397	4269334	3986481	3904795	4370803	4059423	6010588	4222896
	3931215							
100/111/020	3927050	4112845	4308454	3969650	4135636	4304616	4195285	4358010
	4029076	4217899	4347850	4047362	4241691	4361583	4337269	3990360
	4059424	4271735	4414897	4068624	4282247	4433466	3973460	4144618
	4433467	4427307	4206539	4412425	6001190	6003054	6003050	6018576
	6018589	4433469						
100/111/025	3874369	4166621	4392320	3880750	4080553	4403653	4195302	4414383
	3930096	4214848	4424550	3936648	4222902	4427318	4412427	3918122
	3949085	4220271	4433469	3955901	4241695	4433470	3895055	4187126
	3962938	4255331	4433471	3990368	4292828	4461704	3986487	4304618
	4026789	4337270	6001189	4047364	4337271	6003050	4465594	4007486
	4053371	4354057	6018576	4059426	4343025	4141293	4308455	6001190
	4065680	4345418	4135622	4110009	4356222	4147623	4153140	4370806
	4110010	4368783						
100/111/030	3891574	4228827	4138429	3895035	4260297	4147624	4292829	4169644
	3901349	4262331	4161530	3904790	3908090	4290034	4187132	3933578
	3949086	4304621	4206541	3946325	4304620	4200189	4337276	4214850
	3955988	4337275	4225676	3969651	4340965	4452151	3973463	4269339
	4000829	4358015	4456323	4014666	4347854	4461702	4452150	3981461
	4018136	4351770	4465589	4026786	4379014	6001208	4343026	4454684
	4036208	4392322	4465590	4047356	4403654	6010602	4414889	4118068
	4085821	4417662	4127351	4103890	4425920	4138428	6010603	4065678
	4091975	4433473	4446988	4433474	6031562	6013487	4062712	4406592
	4433472							
100/111/035	3874375	4192162	4461701	3897982	4206542	4456324	4220276	6001197
	3921049	4217903	6010605	3939719	4247562	6010606	4465586	3918158
	3936640	4274653	6010608	3955906	4271738	6013488	3911479	4214852
	3969652	4295329	6027710	3973454	4306894	6055167	4036210	4347856
	4014667	4351771	4038587	4392324	4059427	4377386	4000831	4343030
	4053384	4394899	4080556	4417660	4100450	4414384	3990363	4340968
	4091976	4424548	4110003	4427310	4112854	4433476	4169636	4187134
	4141294	4433475	4144599	4446989	4159072	4452143	4166606	4452144
100/126/025	3874389	3966169	4124776	4290040	4385674	4347863	4062719	4217908
	3891578	3986493	4147630	4343051	4445290	4373213	4192138	3939723
	3918145	4047359	4452134					

100/126/030	3891631	4047361	4222910	4358021	4347864	6018600	4169648	4343053
	3918169	4059422	4247568	4380606	4198116	4461697	4135632	4036209
	3949087	4107078	4269345	4433492	4287239	4456321	3955961	
100/126/035	3867283	4364622	4204344	4091971	3954950	4065676	3933571	6018590
	3884332	4427325	4277416	4124773	4000836	4175618	4042230	4345430
	3911489	4456327	4326705	4150620				
100/127/025	3895053	4445291	4351776	4241703	4135609	6055170	4326704	4198085
	3911512	4446994	4380607	4262334	4150621	3986494	6031543	4416396
	3942625							
100/127/030	3897978	4465579	4308456	3969659	3955989	4225686	6051961	4412423
	3927028							
100/127/035	3874374	3946346	4228833	4356229	4380608	6010610	3997428	4347866
	3921055							
100/141/025	3877721	4018140	4169669	4290041	4430791	4032458	4230673	4394925
	3904766	4088780	4187130	4290042	4454685	3981483	3966170	4121693
	3923790	4097361	4192164	4337277	4465596	4159074	6031570	6051980
	3936661	4115482	4214857	4377393	6003052	4241704	4217909	4380610
	3939725	4110011						
100/141/030	3872612	3931212	4121704	4217911	4287243	4445297	4271747	4195299
	3877722	3936629	4147632	4222912	4380611	4433497	4394926	4121706
	3880755	3969660	4144626	4233557	4392329	4445299	4187158	4260304
	3891596	3981479	4153129	4164141	4406609	4448467	4445296	4287242
	3891597	4065679	4166602	4243803	4445295	4456314	4175579	4250644
	3927046	4100443	4115490	6027719	6027720			
100/141/035	3874416	4053381	4144612	4250647	4380612	4454686	4144611	4047360
	3874417	4075491	4150624	4269347	4392331	4456315	4225683	4042224
	3897969	4097371	4164146	4287244	4394927	6001193	3981482	4141279
	3908113	4062721	4166604	4282270	4430792	6003053	4247572	6060009
	3933576	4115492	4192135	4274658	4220291	6018577	4214860	4379007
	3939726	4109996	4195273	4377394	4220289	6027730	3969662	4138434
	4050233							