

URGENT: FIELD SAFETY NOTICE

Intubation ORAL/NASAL Endotracheal Tube

19th February 2025

Dear Valued Customers:

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)

Affected Product Name	Affected Product
TRACHEAL TUBE IVORY UNCUFFED ORAL/NASAL 2.5MM 10/BX	100/105/025
TRACHEAL TUBE IVORY UNCUFFED ORAL/NASAL 3.0MM 10/BX	100/105/030
TRACHEAL TUBE IVORY UNCUFFED ORAL/NASAL 3.5MM 10/BX	100/105/035
TRACHEAL TUBE SILICONISED ORAL/NASAL UNCUFFED 2.0MM 10/BX	100/111/020
TRACHEAL TUBE SILICONISED ORAL/NASAL UNCUFFED 2.5MM 10/BX	100/111/025
TRACHEAL TUBE SILICONISED ORAL/NASAL UNCUFFED 3.0MM 10/BX	100/111/030
TRACHEAL TUBE SILICONISED ORAL/NASAL UNCUFFED 3.5MM 10/BX	100/111/035
TRACHEAL TUBE SILICONIZED CUT-TO-LENGTH. ORAL 3.5MM 10/BX	100/126/035
TRACHEAL TUBE MURPHY EYE UNCUFFED SILICONISED ORAL/NASAL 2.5MM 10/BX	100/127/025
TRACHEAL TUBE MURPHY EYE UNCUFFED SILICONISED ORAL/NASAL 3.0MM 10/BX	100/127/030
TRACHEAL TUBE MURPHY EYE UNCUFFED SILICONISED ORAL/NASAL 3.5MM 10/BX	100/127/035
TRACHEAL TUBE MURPHY EYE UNCUFFED SILICONISED ORAL/NASAL 2.5MM 10/BX	100/141/025
TRACHEAL TUBE MURPHY EYE UNCUFFED SILICONISED ORAL/NASAL 3.0MM 10/BX	100/141/030
TRACHEAL TUBE M/EYE UNCUFFED SILICONISED ORAL/NASAL 3.5MM 10/BX	100/141/035

Please refer to Appendix A for affected product lot numbers.

Customer Required Actions

There is no need to remove an affected Endotracheal tube if it is already in use. However, please review the Instructions for Use with heightened awareness prior to continued use

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 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

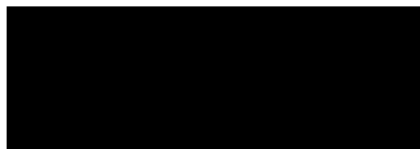
For further inquiries, please contact Smiths Medical using the information provided below:

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,



Vice President of Quality

See below:

Appendix A - Affected product lot numbers
Customer Response Form

Appendix A – Affected product lot numbers

Item Number	Lot Number							
100/105/025	3911500	3969644	4050235	4110012	4159071	4209071	4255323	4308451
	3927026	3986480	4062708	4135634	4166635	4222894	4284465	4337267
	3954958	4014665	4080550	4147621	4190224	4247556	4296990	4345413
100/105/030	3880748	3955939	4050237	4121698	4214842	4304610	6001192	
	3891668	3969646	4059417	4144606	4247557	4337268	6010589	
	3904782	3990354	4062709	4153143	4255324	4343014	6018580	
	3931190	4004638	4077446	4166633	4264607	4345414	6025898	
	3942650	4011059	4091972	4192137	4282245	4354054		
100/105/035	3874397	3931215	3986481	4059423	4190222	4308452	4370803	
	3901353	3954951	4007482	4121695	4222896	4340958	6010588	
	3904795	3973457	4023465	4150613	4269334	4347847		
100/111/020	3884360	4018131	4068624	4144618	4241691	4304616	4377379	4433467
	3927050	4029076	4080552	4166622	4255329	4308454	4412425	4461705
	3936628	4036214	4085815	4187114	4260296	4337269	4414897	
	3969650	4047362	4110000	4195285	4271735	4347850	4417663	
	3973460	4053374	4112845	4206539	4282246	4358010	4427307	
	3990360	4059424	4135636	4217899	4282247	4361583	4433466	
100/111/025	3874369	3986487	4065680	4187126	4296992	4368783	4433470	6018575
	3880750	4007485	4080553	4195302	4304618	4370806	4433471	6018576
	3895055	4007486	4110009	4214848	4308455	4392320	4461704	6027727
	3918122	4018135	4110010	4220271	4337270	4403653	4465594	6055166
	3930096	4026789	4135622	4222902	4337271	4406591	6001189	
	3936648	4042235	4141293	4241695	4343025	4414383	6001190	
	3949085	4047364	4147623	4255331	4345418	4424550	6003051	
	3955901	4053371	4153140	4290031	4354057	4427318	6010585	
	3962938	4059426	4166621	4292828	4356222	4433469	6018574	
100/111/030	3891574	3981461	4085821	4200189	4304620	4358015	4433472	6013487
	3895035	3990362	4091975	4206541	4304621	4364616	4433473	6018594
	3901349	4000829	4103890	4214850	4337274	4370809	4433474	6027712
	3904790	4014666	4127351	4225676	4337275	4377383	4452150	6027714
	3908090	4026786	4138428	4228827	4337276	4379014	4452151	
	3930098	4026787	4138429	4260297	4340964	4392322	4456323	
	3933578	4036208	4141277	4262331	4340965	4403654	4461702	
	3946325	4047356	4147624	4269339	4343026	4406592	4465588	
	3949086	4053382	4161530	4290034	4343027	4414889	4465589	
	3955988	4062712	4169644	4292829	4347854	4417662	4465590	
	3973463	4065678	4187132	4304619	4351770	4425920	6001208	

100/111/035	3874375	3973454	4075489	4169636	4274653	4370811	4427321	6001199
	3891590	3981462	4080556	4187134	4295329	4373209	4433475	6010607
	3897982	3990363	4091976	4192162	4302268	4377386	4433476	6010608
	3911479	4000831	4100450	4206542	4304623	4379005	4446989	6013488
	3918158	4007489	4110003	4214852	4306894	4392324	4452143	6018584
	3921049	4014667	4112854	4217903	4340968	4394899	4452144	6018585
	3936640	4038587	4124778	4220276	4343030	4414384	4456324	6018586
	3939719	4047358	4141294	4247562	4343031	4417660	4461701	6036528
	3946342	4053384	4144599	4250638	4347856	4424548	4465586	
	3955906	4059427	4159072	4260298	4351771	4424549	6001197	
	3969652	4065675	4166606	4271738	4361588	4427310	6001198	
100/126/035	3867283							
100/127/025	3911512							
	3986494							
	4445291							
100/127/030	4225686							
	4465579							
100/127/035	3921055							
	4228833							
	4380608							
100/141/025	3897949	3939725	4018140	4115482	4214857	4241704	4290042	6010587
	3904766	3966170	4097361	4159074	4217909	4255341	4337277	6018579
	3923790	3981483	4110011	4169669	4230673	4290041	4377393	6027729
	6031570							
100/141/030	3891596	3936629	3977857	4118078	4233557	4271747	4394926	4445296
	3891597	3954964	3981479	4147632	4243803	4287242	4406609	4445297
	3927046	3962947	4107074	4217911	4250644	4287243	4433497	
	3931212	3969660	4110007	4222912	4260304	4392329	4445295	
100/141/035	3874417	3939726	4047360	4075491	4118083	4220289	4250647	4274658
	3891587	3969662	4050233	4097371	4144611	4220291	4255346	4282270
	3897969	3981482	4053381	4109996	4150624	4225683	4260305	4287244
	3933576	4042224	4062721	4115492	4166604	4247572	4269347	4370817
	4377394							

URGENT: FIELD SAFETY NOTICE – RESPONSE FORM

Intubation ORAL/NASAL Endotracheal Tube

19th February 2025

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]