

Managing the shortage of neonatal and paediatric endotracheal tubes



SAFETY ALERT 002/25

Issue date:	7 March 2025
Content reviewed by:	ACI Emergency Care Institute, Paediatric Network and Maternity and Neonatal Network, Sydney Children's Hospital Network, Neonatal Emergency Transport Service, HealthShare NSW, CEC Maternity and Paediatric Improvement Leads
Distributed to:	Chief Executives; Directors of Clinical Governance; Director, Regulation and Compliance Unit
KEY MESSAGE:	NSW Health facilities are informed of a global shortage of Smith Medical / ICU Medical neonatal and paediatric Endotracheal Tubes (ETTs)
ACTION REQUIRED BY:	Chief Executives; Directors of Clinical Governance
REQUIRED ACTION:	<ol style="list-style-type: none"> 1. Distribute this Safety Alert to all staff who perform neonatal and/or paediatric intubation and resuscitation, to all staff involved in managing the supply of endotracheal tubes (ETTs), and to all areas in which neonatal or paediatric ETTs are stored. 2. Include this Safety Alert in relevant handovers and safety huddles. 3. Do not destroy or dispose of Smiths Medical ETTs affected by RC-2025-RN-00093-1. Clearly label these devices so that they are identifiable as the affected lots. 4. Escalate any clinical concerns as per Local Health District / Specialty Health Network processes. 5. Report any incidents associated with this shortage into ims+.
We recommend you also inform:	<p>Directors, Managers and Staff of:</p> <ul style="list-style-type: none"> • Medical Services • Nursing and Midwifery • Emergency Departments • Retrieval Services • Maternity and Neonatal Services • Paediatric Units • Operating Theatres/Anaesthetic Services • Rapid Response/CERS teams/Intensive Care Units • NSW Ambulance • Clinical Product Managers • All other relevant clinicians, departments and committees
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html
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Situation

On 19 February 2025, the Therapeutic Goods Administration (TGA) issued a Class II Urgent Medical Device Recall affecting certain lots of Smiths Medical intubation oral / nasal **uncuffed** Endotracheal Tubes (ETTs)(RC-2025-RN-00093-1). This Notice advised that neonatal and paediatric size ETTs (sizes 2.0 to 3.5) may have a smaller internal diameter than expected (average 0.10 mm below the lower specification limits). Not all stock in circulation is affected by this recall notice. The manufacturer has commenced production of new unaffected stock.

The clinical significance of the reported defect is not currently known. To date there have been no serious adverse outcomes reported that are associated with the use of affected ETTs.

Smith Medical is the major supplier of neonatal and paediatric ETTs for NSW Health. The recall has resulted in a shortage of these devices. Therefore, NSW Health has established a group of expert clinicians and managers to minimise disruption and ensure continuation of safe patient care.

Background

ETTs are devices that are used to secure an airway in patients who require mechanical ventilation and/or resuscitation. They are widely used across NSW Health in clinical areas, particularly in Emergency Departments, Neonatal and Paediatric Intensive Care Units (NICU and PICU), Special Care Units (SCU), Maternity Services and Operating Theatres.

The contract for Smith Medical ETTs was recently transferred to ICU Medical, so you may see the supplier information assigned to either of these two companies. Smith Medical ETTs may also be known as 'Portex' tubes.

Cuffed ETTs are unaffected by the recall.

Assessment

As ETTs are an essential component of neonatal and paediatric resuscitation and airway management, and it was determined that destroying all listed batches before establishing an alternate supply would add risk for patients in NSW Health. Therefore, a risk-based approach to managing the recall and subsequent shortages has been established.

- A stocktake audit was undertaken to determine stock levels currently in the system, and to further identify locations of stock that can be moved to sites with higher need. Ongoing weekly audits will also be required until stock levels improve.
- HealthShare NSW has been working with Smith Medical/ICU Medical and other suppliers to obtain as much unaffected stock as possible.
- An escalation pathway is being established for Local Health Districts and Specialty Health Networks to prioritise supply of unaffected ETTs to areas of urgent need.
- Investigations are being undertaken to determine the clinical significance of the smaller internal diameter and the impact this may have on the gas flow through the affected ETTs.

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Recommendations

1. Do not destroy or dispose of Smiths Medical ETTs affected by RC-2025-RN-00093-1.
2. Quarantine and securely store affected stock, clearly labelling them for easy recognition.
3. Local Health Districts / Specialty Health Networks should establish governance processes to closely monitor stock levels, manage stock rotation within their area, and refer to the escalation process as required.
4. Consider using a Supraglottic Airway (SGA) for resuscitation in the birthing environment.
5. Prioritise unaffected stock for babies requiring ventilation.
6. Where unaffected stock is not available and intubation is clinically indicated for the benefit of the patient, clinicians are supported to use affected stock. If affected stock is used, ensure device and batch details are recorded in the patient's healthcare record.
7. Before intubation with **all** ETTs, pause and ensure the following:
 - a. An appropriately sized suction catheter passes easily in and out of the ETT
 - b. A stylet, if used, passes freely in and out of the ETT.
8. If an issue is found with an ETT, report the incident in imst+, ensuring the ETT product and batch details are recorded in appropriate fields. Retain the device and contact cec-recalls@health.nsw.gov.au for further instructions.