

**Issue date**  
19 April 2022

**Distributed to:**

Chief Executives  
Directors of Clinical Governance  
Director, Regulation and Compliance Unit

**Action required by:**

Chief Executives  
Directors of Clinical Governance

**We recommend you also inform:**

Directors/Managers of all units where neonates may require intubation:

- Surgical / Anaesthetic Services
- Emergency and Retrieval Services
- NICU / PICU / ICU
- Delivery wards, Maternity Services

**Expert Reference Group**

**Content reviewed by:**

HealthShare NSW

Representatives from:

- Agency for Clinical Innovation
- Ministry of Health, State Preparedness and Response Branch
- Neonatologist
- Paediatric Emergency Physician

**Clinical Excellence Commission**

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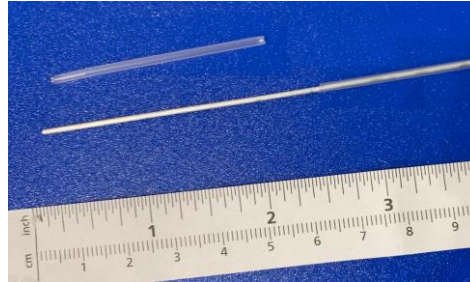
Intranet: <http://internal.health.nsw.gov.au/quality/sabs>

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## Risk of retained intubating stylet fragment in neonates

### Situation

A recent clinical incident in Australia and two incident reports in NSW since 2020, have highlighted the potential risk of shearing and retention of the stylet sheath during neonatal endotracheal tube (ETT) intubation.



*Fragment of stylet sheath*

This is a rare but life-threatening complication that may lead to partial or complete airway obstruction, impaired ventilation and additional invasive procedures.

### Background

Intubating stylets (also known as “introducers”) are flexible, plastic coated (sheathed) wires used to assist with the correct positioning of an ETT, particularly in neonates. The plastic sheath, which is not bonded to the stylet wire, is designed to minimise airway trauma if the stylet extends beyond the tip of the ETT and reduce friction during stylet insertion and withdrawal from the ETT.

Whilst no definitive cause of shearing of the stylet sheath is reported in the literature<sup>a-c</sup>, it is suggested that repeated shaping of the stylet, reuse and friction between the ETT and the stylet during insertion and removal may be contributing factors. Friction may be highest if the stylet is a tight fit within the ETT.

### Assessment

Due to the serious risk involved with retained fragments, it is important clinicians are aware of prevention strategies and can recognise and manage retained stylet sheath fragments in the ETT or airway.

Prevention strategies may include:

- Follow the stylet’s Instructions for Use when selecting the stylet size recommended for the size of the ETT
- Exercise additional caution using a stylet with an ETT less than 3mm
- Use a new stylet if there are multiple intubation attempts or re-shaping of the stylet is required to correctly place an ETT.

Recognition of retained stylet fragment(s) may include:

- Acute airway obstruction
- Airway injury
- Foreign body(s) on chest x-ray
- Partial or complete ETT occlusion
- Higher than expected airway ventilation pressures.

### Clinical Recommendations

- Where possible, a clinician experienced in airway management should be present during neonatal intubation
- Assess the need for the use of an intubating stylet. Consider alternate techniques to guide the ETT to the correct position
- Follow the stylet's Instructions for Use, noting:
  - Single use
  - Check stylet size compatibility with the selected ETT size
- Exercise additional caution with ETTs less than 3mm, as these sizes may be outside the specifications for use of a stylet
- Inspect the stylet sheath integrity before use
- Avoid repeated sharp bending, maintain a smooth shape of the stylet
- Where possible do not re-use a stylet. Consider availability and preparation of additional stylets if there are multiple attempts to intubate
- Inspect the stylet sheath integrity after use
- Obtain a post intubation chest x-ray with attention to the possibility of a retained sheath fragment.

If stylet sheath retention is suspected:

- Do not immediately extubate the patient if the infant has stable ventilation
- Seek immediate expert assistance including activation of a local CERS response
- Obtain an urgent chest x-ray. Request immediate review by radiologist for possible sheath fragment retention. The fragment may be located within the ETT and/or below the ETT
- Note, use of a suction catheter or administration of surfactant may push the fragment lower into the bronchial tree.

### Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians, clinical departments where neonatal intubation may occur
2. Include this information in relevant handovers and safety huddles
3. Undertake a local risk assessment and develop strategies to mitigate the risk of stylet fragment retention
4. Liaise with the local Clinical Product Managers to ensure the size of the stylets are compatible with the ETTs in use
5. Escalate any concerns relating to this issue to service directors or managers
6. Report any incidents associated with these devices into [ims+](#) and [TGA](#)
7. Confirm receipt and distribution of this notice within 72 hours to [CEC-Recalls@health.nsw.gov.au](mailto:CEC-Recalls@health.nsw.gov.au).

### References

- a) Chiou HL, Diaz R, Orlino E Jr, Poulain FR: Acute airway obstruction by a sheared endotracheal intubation stylet sheath in a premature infant. *J Perinatol.* 2007, 27:727-9.
- b) Gray MM, Umoren RA, Harris S, Strandjord TP, Sawyer T. Use and perceived safety of stylets for neonatal endotracheal intubation: a national survey. *J Perinatol.* 2018 Oct;38(10):1331-1336.
- c) Viswanathan S, Rodriguez Prado Y, Chua C, Calhoun DA. Extremely Preterm Neonate with a Tracheobronchial Foreign Body: A Case Report. *Cureus.* 2020 Apr 13;12(4): e7659.