

Medical Device Alert

Immediate action

Ref: MDA/2009/063 Issued: 14 October 2009 at 14:30

Device

Endotracheal tube. Portex uncuffed paediatric tracheal tubes, manufactured by Smiths Medical.



Problem

A manufacturing defect has resulted in some tubes having an internal diameter slightly smaller than indicated on the labelling.

The small diameter may cause a problem when suctioning a patient, and may also increase airway resistance, compromising the ability to ventilate the patient.

Action by

All staff responsible for the use of these devices.

CAS deadlines

Action underway: 21 October 2009

Action complete: 04 November 2009

Action

- Check stock to identify affected batches.
- Contact Smiths Medical to arrange for their return and replacement or credit.
- While waiting for replacement product, or if no replacement/alternatives are available, clinicians should follow the recommendations for suction catheter sizes on the Smiths Medical size guidance chart given in their [Field Safety Notice](#).

Contact

Manufacturer

UK Customer Services
Smiths Medical International Limited

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E-mail: ukcs@smiths-medical.com

[Link to full Medical Device Alert](#)

<http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON059921>