

Medical Device Alert

Ref: MDA/2012/002 Issued: 19 January 2012 at 14:30

Device

Tracheostomy tubes: Bivona[®] Neonatal, Pediatric and Flextend.

Manufactured by Smiths Medical.

Lot numbers from 1631477 to 1923406 inclusive.

Problem	Action	
<p>Incorrectly connected accessories may be difficult to remove, requiring excessive force to disconnect. This may cause the tube to dislodge, requiring it to be changed.</p> <p>The manufacturer has initiated a recall of affected tubes.</p> <p>The manufacturer issued a Field Safety Notice (FSN) – dated 15 November 2011 (see appendix 2) – but has not had confirmation from all users that they have received and acted on this information.</p>	<ul style="list-style-type: none"> • See appendix 1 for affected reorder numbers, and NHS supply chain codes where applicable. • Locate and quarantine all unused affected devices. • Complete and return the Smiths Medical confirmation form, even if you no longer have affected units in stock. • Return all unused affected devices as described in the Field Safety Notice issued by Smiths Medical. <p>For patients with affected tubes in situ:</p> <ul style="list-style-type: none"> • Review the advice on correct use provided in the ‘Customer Information Bulletin’ (in the FSN) and “Tracheostomy – Neo-Pedi” guidance video on the Smiths Medical website. 	
Action by		
<p>All staff responsible for the care of neonatal and paediatric patients with tracheostomy tubes.</p> <p>Personnel involved in the purchase, supply and distribution of these devices.</p>	<th data-bbox="801 1581 1477 1644">Contact</th>	Contact
CAS deadlines	<p>Manufacturer Philip York, Smiths Medical Tel: 01923 241 411 Fax: 01233 722 153 Email: ukcs@smiths-medical.com</p>	
<p>Action underway: 02 February 2012</p> <p>Action complete: 19 March 2012</p>		

[Link to full Medical Device Alert](#)

www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON140753