

**SAFETY NOTIFICATION: POTENTIAL
DETERIORATION OF BIVONA SILICONE
TRACHEOSTOMY TUBES**



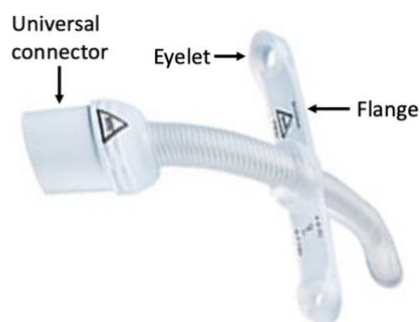
BACKGROUND:

There have been reported incidents of Bivona silicone tracheostomy tubes deteriorating, and in some cases breaking, leading to risks to individuals

ISSUE:

There are reports of Bivona silicone tracheostomy tubes breaking at various points:

- Eyelet of the flange
- Base of the flange
- Junction with the universal connector



ACTIONS TO BE TAKEN:

- Apply increased vigilance in all tracheostomy tube care
- Check all visible parts of the tracheostomy tube and its connectors for any signs of wear or breakage on **at least a daily basis**
- Record the batch and lot number for all tracheostomy tubes used
- When the tracheostomy tube is secured, twill fabric tape should be in contact with the tube eyelets, not Velcro
- Clean and reuse tracheostomy tubes only as per manufacturers' guidance
- Replace any tracheostomy tube that is damaged or showing signs of wear
- Keep any damaged or degraded tracheostomy tube for subsequent review
- Escalate any concerns or issues with a tracheostomy tube to usual tracheostomy-related healthcare point of contact
- For healthcare professionals: in the event of a problem, as appropriate submit
 - A clinical incident report
 - MHRA Yellow Card form: <https://yellowcard.mhra.gov.uk>
 - NHS Supply Chain product complaint: <https://www.supplychain.nhs.uk/contact/submit-product-complaint/>
 - **And** email ICU Medical Customer Service: ukcs@smiths-medical.com