

## URGENT MEDICAL DEVICE NOTIFICATION

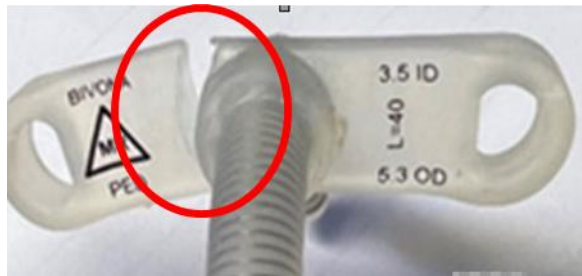
**Bivona® Aire-Cuf®, TTS™, Uncuffed, Mid-Range Neonatal/Pediatric Tracheostomy Tube(s) and Bivona Aire-Cuf®, TTS™, Cuffless FlexTend™, TTS™ FlexTend™ Adult Tracheostomy Tube(s)**

Dear Customer,

Smiths Medical has issued an Urgent Field Safety Notice to notify you of a potential defect with the following Bivona® Neonatal/Pediatric and Adult Tracheostomy products.

### Issue:

Smiths Medical has identified that the securement flange of specific lots of the Bivona® Neonatal/Pediatric and Adult Tracheostomy products may tear because of a manufacturing defect. See picture below for an example of a torn flange.



### Potential Risk:

If the flange on the item is torn or broken, the tracheostomy tube may not stay in position in the trachea. This can lead to tracheostomy displacement or decannulation. Either event may result in an inability to properly ventilate or protect the airway. Either can contribute to a catastrophic adverse event.

### Affected Product:

Please contact your local ProResp office to verify if your product is affected or with any questions you have regarding this Field Safety Notice.

### Customer Required Actions:

When using the device, all instructions, including warning and cautions contained in the Instructions for Use Documentation must be followed with heightened awareness.

Thank you very much for your attention to this matter, and please do not hesitate to contact your local ProResp office with any questions or concerns.