



Food and Drug Branch – Device Recalls

**California Device Recall Information Sheet**

**Smiths Medical ASD Inc. Recalls Pediatric Tracheostomy Tube TTS Flextend Straight Neck**

Recall Date	Product Description	Recalling Firm	Recall Reason
9/4/2024	<b>Pediatric Tracheostomy Tube 2.5mm Tts Flextend Straight Neck</b> Product Code/List Number/Item Code: 67PFSS25	<b>SMITHS MEDICAL ASD INC.</b> Minneapolis, Mn	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.
9/4/2024	<b>Pediatric Tracheostomy Tube 3.0mm Tts Flextend Straight Neck</b> Product Code/List Number/Item Code: 67PFSS30	<b>SMITHS MEDICAL ASD INC.</b> Minneapolis, Mn	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.
9/4/2024	<b>Pediatric Tracheostomy Tube 3.5mm Tts Flextend Straight Neck</b> Product Code/List Number/Item Code: 67PFSS35	<b>SMITHS MEDICAL ASD INC.</b> Minneapolis, Mn	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.

9/4/2024	<b>Pediatric Tracheostomy Tube 4.0mm Tts Flextend Straight Neck</b> Product Code/List Number/Item Code: 67PFSS40	<b>SMITHS MEDICAL ASD INC.</b> Minneapolis, Mn	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.
9/4/2024	<b>Pediatric Tracheostomy Tube 4.5mm Tts Flextend Straight Neck</b> Product Code/List Number/Item Code: 67PFSS45	<b>SMITHS MEDICAL ASD INC.</b> Minneapolis, Mn	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.
9/4/2024	<b>Pediatric Tracheostomy Tube 5.0mm Tts Flextend Straight Neck</b> Product Code/List Number/Item Code: 67PFSS50	<b>SMITHS MEDICAL ASD INC.</b> Minneapolis, Mn	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.
9/4/2024	<b>Pediatric Tracheostomy Tube 5.5mm Tts Flextend Straight Neck</b> Product Code/List Number/Item Code: 67PFSS55	<b>SMITHS MEDICAL ASD INC.</b> Minneapolis, Mn	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.

Recall Class	Product Identification	Distribution	Affected Dates
I	<b>Pediatric Tracheostomy Tube 2.5mm Tts Flextend Straight Neck</b> UDI-DI: 10351688518668	Nationwide	August 2024 and prior
I	<b>Pediatric Tracheostomy Tube 3.0mm Tts Flextend Straight Neck</b> UDI-DI: 10351688518675	Nationwide	August 2024 and prior
I	<b>Pediatric Tracheostomy Tube 3.5mm Tts Flextend Straight Neck</b> UDI-DI: 10351688518682	Nationwide	August 2024 and prior
I	<b>Pediatric Tracheostomy Tube 4.0mm Tts Flextend Straight Neck</b> UDI-DI: 10351688518699	Nationwide	August 2024 and prior
I	<b>Pediatric Tracheostomy Tube 4.5mm Tts Flextend Straight Neck</b> UDI-DI: 10351688518705	Nationwide	August 2024 and prior
I	<b>Pediatric Tracheostomy Tube 5.0mm Tts Flextend Straight Neck</b> UDI-DI: 10351688518712	Nationwide	August 2024 and prior
I	<b>Pediatric Tracheostomy Tube 5.5mm Tts Flextend Straight Neck</b> UDI-DI: 10351688518729	Nationwide	August 2024 and prior

For additional information, please visit the [FDA website](#).