



[Food and Drug Branch – Device Recalls](#)

California Device Recall Information Sheet

Smiths Medical ASD Inc. Recalls PORTEX Bivona Tracheotomy Silicone Tube Standard Flextend Plus

Recall Date	Product Description	Recalling Firm	Recall Reason
9/4/2024	Paed. Tracheostomy Tube 2.5mm Standard Flextend Plus Product Code/List Number/Item Code: 60PFS25	SMITHS MEDICAL ASD INC. 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	Paed. Tracheostomy Tube 3.0mm Standard Flextend Plus Product Code/List Number/Item Code: 60PFS30	SMITHS MEDICAL ASD INC. 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	Paed. Tracheostomy Tube 3.5mm Standard Flextend Plus Product Code/List Number/Item Code: 60PFS35	SMITHS MEDICAL ASD INC. 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	Paed. Tracheostomy Tube 4.0mm Standard Flextend Plus Product Code/List Number/Item Code: 60PFS40	SMITHS MEDICAL ASD INC. 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	Paed. Tracheostomy Tube 4.5mm Standard Flextend Plus Product Code/List Number/Item Code: 60PFS45	SMITHS MEDICAL ASD INC. 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	Paed. Tracheostomy Tube 5.0mm Standard Flextend Plus Product Code/List Number/Item Code: 60PFS50	SMITHS MEDICAL ASD INC. 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	Paed. Tracheostomy Tube 5.5mm Standard Flextend Plus Product Code/List Number/Item Code: 60PFS55	SMITHS MEDICAL ASD INC. 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	Paed. Tracheostomy Tube 2.5mm Standard Flexend Plus UDI-DI: 15021312005837	Nationwide	August 2024 and prior
I	Paed. Tracheostomy Tube 3.0mm Standard Flexend Plus UDI-DI: 15021312005844	Nationwide	August 2024 and prior
I	Paed. Tracheostomy Tube 3.5mm Standard Flexend Plus UDI-DI: 15021312005851	Nationwide	August 2024 and prior
I	Paed. Tracheostomy Tube 4.0mm Standard Flexend Plus UDI-DI: 15021312005868	Nationwide	August 2024 and prior
I	Paed. Tracheostomy Tube 4.5mm Standard Flexend Plus UDI-DI: 15021312005875	Nationwide	August 2024 and prior
I	Paed. Tracheostomy Tube 5.0mm Standard Flexend Plus UDI-DI: 15021312005882	Nationwide	August 2024 and prior
I	Paed. Tracheostomy Tube 5.5mm Standard Flexend Plus UDI-DI: 15021312005899	Nationwide	August 2024 and prior

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

