

Table 1. Recalls Relevant to Otolaryngology in the Last Year

| Product | Brand (Company) | Date (month/year) | Reasons | Lawsuit and Compensation or Patient Harm |
|-------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------|----------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| Tracheostomy Tubes | Bivona (Smiths Medical) | 08/24 | May tear causing displacement or decannulation | 35 serious injuries; 1 death |
| ENT Ultra Round Steel Cutting Bur | Medtronic Xomed | 07/24 | Past expiration date | 1 unit, Canada |
| Stryker iBur Coarse Diamond Round, Precision Round, Diamond Round, Diamond Match Head, Precision Match Head | Stryker Corporation | 07/24 | Exhibit temperatures higher than specification where the bur shank meets the distal bushing resulting in minor tissue/structure damage | 1226 + 2507 + 1706 + 1227 +1612 + 5031 + 2670 +1171 + 2507 + 3673 units, U.S. and worldwide |
| McGrath Mac Video Laryngoscope, MAC EMS Video Laryngoscope | Covidien | 07/24 | Battery management system may deplete below the deign threshold -> thermal event -> explosion. | 75,544 units + 10,449 units, U.S. and worldwide |
| NIM Vital Nerve Monitoring systems | Medtronic Xomed, Inc | 06/24 | Potential for false negative response | 7,804 units, U.S. and worldwide |
| Portex BLUperc Percutaneous Dilation Procedural Trays with BLUselect trach tubes | Smiths Medical ASD Inc. | 06/24 | Disconnection of the pilot balloon from the tracheostomy inflation line. | 41691 + 12234 units, worldwide |
| SubG ET Tubes w/ Subglottic Suction/Kits | Medline (Medline Industries) | 05/24 | Detached and/or torn from the main tube leading to moisture buildup, loss of pressure, or inability to inflate. | Not aware of any serious health consequences |
| Inspire Model 3028, IV Implantable Pulse Generator | Inspire Medical Systems Inc. | 05/24 | Electrical leakage in the sensing circuit which causes a system malfunction and requires a revision surgery | 24 devices, U.S. and Germany |
| Mi1250 SYNCHRONY 2 CI | MED-EL Elektromedizinische Gereate | 04/24 | Higher probability of a crack within the internal electronics substrate causing a non-functional device | 7 devices in NC, U.S. |
| LASER Application Instrument | Karl Storz Endoscopy | 04/24 | No specific evidence of a validated reprocessing method, leading to increased infection risk | 85, U.S. and Argentina |
| CPAP and BIPAP Masks with Magnets | Mojo, Mojo 2, iQ 2, Phantom 2 (Sleepnet Corp.) | 03/24 | Magnet could interfere with the performance or the position of the implant | N/A |
| 8S RA Super-Sharp Round carbide dental bur | Brasseler USA I Lp | 01/24 | Bur to not adequately latch in the handpiece. | 440 burs, U.S. and Canada |