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Class 2 Device Recall Guedel Airway



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Class 2 Device Recall Guedel Airway



Date Initiated by Firm	June 15, 2026
Date Posted	August 14, 2026
Recall Status ¹	Open ³ , Classified
Recall Number	Z-2953-2026
Recall Event ID	99284 ²³
Product Classification	Airway, oropharyngeal, anesthesiology ²⁴ - Product Code CAE ²⁵
Product	One-Piece Guedel Airway, size 000, ISO 3.5, Light Green. Oropharyngeal Airway Device.
Code Information	REF: 1000035; Single Unit UDI: 5030267049844; Case UDI: 05030267044528; Lot No. 32190425, 32213076, 32221283, 32307261, 32317627, 32321305, 32513841, 32517565.
FEI Number	1000120301
Recalling Firm/ Manufacturer	Intersurgical Inc 5010 Campuswood Dr Ste 102 East Syracuse NY 13057-1561
For Additional Information Contact	Customer Support 800-828-9633
Manufacturer Reason for Recall	Devices could potentially be occluded or partially occluded.
FDA Determined Cause ²	Process control
Action	An URGENT MEDICAL DEVICE RECALL notification dated 6/12/26 was mailed and to consignees. The notification instructs consignees to immediately discontinue use of affected devices and quarantine any stock remaining. If product has been further distributed a copy of the recall notification is to be forwarded and collect their affected product. To coordinate return of goods contact Intersurgical Customer Support at 800-828-9633 from Monday through Thursday, 8:00 AM to 3:00 PM EST, and follow the provided instructions.
Quantity in Commerce	1,575 units
Distribution	US Nationwide distribution in the states of CT, FL, IN, MI, OH & VA.
Total Product Life Cycle	TPLC Device Report ²⁶

¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#)²⁷.

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

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