



[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵

Class 2 Device Recall Guedel Airway



[510\(k\)](#)⁷ [DeNovo](#)⁸ [Registration & Listing](#)⁹ [Adverse Events](#)¹⁰ [Recalls](#)¹¹ [PMA](#)¹² [HDE](#)¹³ [Classification](#)¹⁴ [Standards](#)¹⁵
[CFR Title 21](#)¹⁶ [Radiation-Emitting Products](#)¹⁷ [X-Ray Assembler](#)¹⁸ [Medsun Reports](#)¹⁹ [CLIA](#)²⁰ [TPLC](#)²¹

[New Search](#)

[Back to Search Results](#)

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-2952-2026
Recall Event ID	99284 ²³
Product Classification	Airway, oropharyngeal, anesthesiology ²⁴ - Product Code CAE ²⁵
Product	One-Piece Guedel Airway, size 00, ISO 5.0, Blue. Oropharyngeal Airway Device.
Code Information	REF: 1100050; Single Unit UDI: 5030267050185; Case UDI: 05030267044450; Lot No. 32121232, 32208193, 32400267, 32403734, 32408819, 32409672, 32416545, 32427064, 32605471, 32606405, 32606850, 32607154.
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	21,269 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.

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <https://www.fda.gov/>
4. <https://www.fda.gov/Medical-Devices>
5. <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
8. </scripts/cdrh/cfdocs/cfpmn/denovo.cfm>
9. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
10. </scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
11. </scripts/cdrh/cfdocs/cfRES/res.cfm>
12. </scripts/cdrh/cfdocs/cfPMA/pma.cfm>
13. </scripts/cdrh/cfdocs/cfHDE/hde.cfm>
14. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>
15. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
16. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>
19. </scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>
20. </scripts/cdrh/cfdocs/cfClia/Search.cfm>
21. </scripts/cdrh/cfdocs/cfTPLC/tpic.cfm>
22. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports>
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=99284
24. </scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=CAE>
25. </scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=CAE>
26. </scripts/cdrh/cfdocs/cfTPLC/tpic.cfm?id=CAE>
27. <https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall>

Page Last Updated: 08/31/2026

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [العربية](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [فارسی](#) | [English](#)

[Accessibility Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA](#) [No FEAR Act](#) [Nondiscrimination](#) [Website Policies](#) / [Privacy](#)



U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
[Contact FDA](#)



[For Government For Press](#)

[Combination Products Advisory Committees](#) [Science & Research](#) [Regulatory Information](#) [Safety Emergency Preparedness](#) [International Programs](#) [News & Events](#) [Training and Continuing Education](#) [Inspections/Compliance](#) [State & Local Officials](#) [Consumers](#) [Industry Health Professionals](#) [FDA Archive](#) [Vulnerability Disclosure Policy](#)



U.S. Department of **Health & Human Services**

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <https://www.fda.gov/>
4. <https://www.fda.gov/Medical-Devices>
5. <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>
6. </scripts/cdrh/devicesatfda/index.cfm>

7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tpic.cfm
22. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports>
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=99284
24. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=CAE
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=CAE
26. /scripts/cdrh/cfdocs/cfTPLC/tpic.cfm?id=CAE
27. <https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall>