Accepted Manuscript online: 2026-10-10 Article published online: 2026-10-21

Original article

Indication-Specific Adverse Events and Temporal Trends of Lumen-Apposing Metal Stents: A National Postmarketing Surveillance Analysis (2020–2025)

Ishaan Vohra[1], Muhammad K. Hasan[2], Harishankar Gopakumar[3], Dennis Yang[2], Deepanshu Jain[2], Natalie Cosgrove[2], Maham Hayat[2], Ranya Ahmed[2,4], Abdul Mohammed[2], Zubair Khan[2], Carlos-Rodriguez Bertran[2], Mustafa A. Arain[2]

Affiliation addresses are listed at the end of the article.

CC BY

ABSTRACT

Background and Aims The AXIOS stent is a lumen-apposing metal stent widely used for endoscopic ultrasound-guided drainage of pancreatic fluid collections, biliary drainage, and gastroenterostomy. We analyzed device problems and patient adverse events reported to the FDA Manufacturer and User Facility Device Experience (MAUDE) database (2020–2025) with indication-specific risk stratification.

Methods We performed a retrospective analysis of 1775 AXIOS adverse event reports from the FDA MAUDE database, systematically classified by procedural indication, device problem, and patient outcome. Each report was assigned to a single highest-severity category, and within-indication proportions were calculated.

Results Annual reports increased by 232%, from 144 in 2020 to 478 in 2025. The indications comprised pancreatic drainage (46.2%), biliary drainage (35.7%), and gastroenterostomy (9.5%). Device problems included positioning/malpositioning (59.0%), distal flange activation failure (19.4%), migration (7.3%), and proximal detachment (4.5%). Gastroenterostomy carried the highest within-indication proportions of mortality (11.8%), perforation (6.5%), and infection (4.1%), exceeding biliary (3.9%, 6.3%, 1.4%) and pancreatic drainage (2.3%, 3.7%, 1.5%).

Conclusions AXIOS adverse event reporting increased by 232% from 2020 to 2025, reflecting expanding utilization and enhanced surveillance. Gastroenterostomy carried the highest within-indication burden of serious adverse events. The marked rise in distal flange activation failures—coinciding with December 2025 manufacturer field safety notice—demonstrates postmarketing surveillance value and underscores the need for indication-specific risk stratification and prospective registries capturing operator- and device-level detail that passive surveillance cannot provide.

Keywords lumen-apposing metal stent, gastroenterostomy, adverse events, postmarketing surveillance, patient safety

received July 15, 2026 | **accepted after revision** October 10, 2026 | **accepted manuscript online** October 10, 2026 | **article published online** 2026

Bibliography Endosc Int Open 2026; a29796046 **DOI** 10.1055/a-2979-6046 **Art ID** EIO-2026-07-4410-OA

© 2026. The Author(s). Georg Thieme Verlag KG, Oswald-Hesse-Straße 50, 70469 Stuttgart, Germany

Correspondence Dr. Ishaan Vohra, MD, Gastroenterology, University of Illinois Chicago College of Medicine at Peoria, Peoria, Illinois 61605, United States, Email: ishvohra28@gmail.com

Introduction

Endoscopic ultrasound (EUS)-guided transmural interventions have fundamentally altered therapeutic approaches for pancreatic-biliary diseases, including pancreatic fluid collections, biliary obstruction, gastric obstruction, and gastroenteric access.[1,2] Central to this revolution is the development of lumen-apposing metal stents (LAMS), which facilitate creation and maintenance of transmural anastomoses between luminal structures.[3,4] The AXIOS stent system (Boston Scientific Corporation, Marlborough, MA), introduced in 2011–2012, represents the first and most widely adopted LAMS device, distinguished by its bilateral anchor flange design and electrocautery-enhanced delivery system.[5–7]

AXIOS stents have demonstrated clinical efficacy across multiple indications. For pancreatic walled-off necrosis (WOPN) and pseudocyst drainage, EUS-guided drainage has supplanted surgical and percutaneous approaches, offering comparable efficacy with reduced morbidity and shorter hospital stays, with LAMS offering ease of deployment and a larger lumen for drainage compared to plastic stents.[8,9] In malignant gastric outlet obstruction, EUS-guided gastroenterostomy (EUS-GE) provides faster

oral intake resumption and reduced reintervention rates compared with enteral stenting.[10,11] For malignant biliary obstruction, EUS-guided choledochoduodenostomy has emerged as an effective alternative when endoscopic retrograde cholangiopancreatography (ERCP) fails, with comparable technical success and stent patency.[12,13] In addition, EUS-guided gallbladder drainage offers a minimally invasive approach for definitive gallbladder drainage in nonoperative surgical candidates.[6]

Despite widespread adoption, comprehensive safety data remain fragmented. Published studies predominantly consist of single-center series or meta-analyses with heterogeneous outcome reporting and variable follow-up durations.[9,14–16] Adverse events, including bleeding, perforation, stent migration, and infection, have been documented, with reported rates varying widely based on indication, operator experience, and procedural technique.[9,17–21] Critically, most studies lack sufficient power to detect indication-specific risk profiles or temporal trends in device performance as utilization expands beyond expert centers.

The FDA Manufacturer and User Facility Device Experience (MAUDE) database provides a unique opportunity to examine real-world safety signals through postmarket surveillance.[22] Previous MAUDE analyses have identified important safety patterns for LAMS devices, including bleeding, migration, and deployment-related adverse events, although comprehensive AXIOS-specific analyses stratified by indication and temporal trends remain limited.[23] Furthermore, rapid expansion of LAMS indications and increasing operator experience necessitate temporal trend analysis to distinguish evolving practice patterns from inherent device-related risks.[24–27] Understanding indication-specific complication profiles is essential for evidence-based clinical decision-making, informed consent, and risk mitigation strategies. We hypothesized that adverse event patterns and complication rates would vary significantly across procedural indications and that temporal trends would reveal evolving safety profiles as clinical experience matured. This study systematically analyzed 1775 AXIOS adverse event reports from the FDA MAUDE database (2020–2025) to characterize indication-specific risks, temporal trends, device-related problems, and patient outcomes in contemporary practice.

Methods

Data Source and Extraction

We conducted a comprehensive analysis of adverse events associated with AXIOS stents using the FDA MAUDE database, a publicly accessible passive surveillance system used to collect medical device adverse event reports from manufacturers, healthcare facilities, and healthcare professionals.[28] MAUDE database files spanning January 2020 through December 2025 were systematically queried, and all reports listing "AXIOS" in the brand name field were extracted and compiled. The study window was defined a priori to encompass a minimum of five complete calendar years of MAUDE reporting, a duration sufficient to distinguish sustained temporal trends from year-to-year variation in a passive surveillance system; all complete annual files available at the time of query were included, yielding a six-year window spanning the period of broad LAMS adoption across all major procedural indications.

The initial compiled dataset contained 1811 records. Thirty-five rows representing MAUDE database disclaimer and footer text rather than adverse event reports were removed, yielding 1776 reports. Following duplicate removal based on FDA Report Number (1 duplicate identified), 1775 unique adverse event reports remained. All reports were included in the analysis to maximize comprehensiveness, including 108 events with documented event dates prior to 2020 that were reported within the 2020–2025 database files. For temporal trend analyses examining year-over-year changes, we focused on the 1667 events with event dates from January 1, 2020 to December 31, 2025. Event dates in the 2025 dataset extended through December 10, 2025, representing approximately 94% of the calendar year. Two further checks were performed. Report-number structure was examined for MAUDE follow-up (supplemental) reports; all identifiers conformed to either the standard manufacturer registrant–year–sequence format or the voluntary MedWatch format, with no supplemental suffix present, and no collapsing of index and follow-up reports was required. Records sharing byte-identical narrative text under distinct report numbers were also screened; 10 such pairs were identified and individually reviewed.

Event Classification

Each adverse event report underwent systematic classification by analyzing multiple data fields including Event Text (narrative description), Device Problem (manufacturer-coded categories), and Patient Problem (clinical outcome codes). A standardized algorithmic approach was developed and uniformly applied to all reports.

Procedural indication was classified through keyword detection in event narratives as: (1) pancreatic pseudocyst or WOPN drainage (keywords: "pseudocyst," "WOPN," "walled-off necrosis," "pancreatic fluid collection," "necrosectomy"); (2) gastroenterostomy (keywords: "gastroenterostomy," "gastric outlet obstruction," "GOO," "duodenal obstruction"). This category encompasses EUS-GE for gastric outlet obstruction and EUS-directed transgastric ERCP (EDGE) procedures where an LAMS is used to facilitate gastric remnant access in a patient with a Roux-en-Y gastric bypass; (3) biliary drainage, encompassing both common bile duct drainage (choledochoduodenostomy, hepatogastrostomy) and gallbladder drainage (cholecystostomy) (keywords: "choledochoduodenostomy," "hepatogastrostomy," "biliary drainage," "bile duct," "cholangiocarcinoma," "gallbladder," "cholecystitis," "cholecystostomy"); or (4) not specified when procedural context was ambiguous or absent.

Procedural approach (transgastric vs. transduodenal) was assessed by screening narratives for explicit anatomical terms. However, approach was inconsistently documented and frequently ambiguous: many narratives referenced both terms or neither, and approach was strongly confounded with procedural indication. Approach-specific outcome analysis was therefore not pursued (**Supplementary Fig. 1** [available in online version only]). Stent type was categorized as Hot AXIOS (electrocautery-enhanced delivery), Cold AXIOS (standard delivery), or type not specified. Stent size (diameter × length in millimeters) was extracted when

© 2026. The Author(s).

explicitly documented; however, size was recorded in only a minority of reports, precluding size-stratified outcome analysis.

Device Problems were classified using both the standardized Device Problem field and free-text Event Text analysis. Categories included: positioning/malpositioning problems, distal flange activation failures, proximal flange detachment issues, stent migration/dislodgement, material integrity problems, premature deployment, breakage, and difficulty with stent removal. Distal flange activation failures were identified by the keywords "Activation Failure" or "Activation Problem," representing technical problems with electrocautery-enabled distal flange deployment. Proximal flange detachment issues were identified by the keyword "Detachment," representing premature release or separation of the proximal anchor flange.

Patient outcomes were determined through systematic keyword searching of Event Text and Patient Problem fields. Outcomes classified included: death (mortality was identified through Event Text analysis using death-related keywords: "death," "died," "deceased," "fatal," "mortality," "passed away," explicitly excluding "expired" which consistently referred to device expiration dates rather than patient mortality); bleeding/hemorrhage; perforation; and infection/sepsis/peritonitis. Events coded as "No Clinical Signs, Symptoms, or Conditions" without other adverse outcomes were classified as device malfunctions without patient harm. Multiple outcomes could be coded for individual events. Each report was assigned to a single, highest-severity adverse event category (mortality > perforation > bleeding > infection > migration), so categories are mutually exclusive; within-indication proportions therefore reflect the report's primary adverse event. All classifications were performed using the standardized algorithm. To assess classification accuracy, a 10% random sample (n = 178) underwent independent review against the algorithm output, demonstrating high concordance for procedural indication and patient mortality.

Statistical Analysis

Descriptive statistics were calculated as frequencies and percentages for categorical variables. Temporal trends were assessed by stratifying the 1667 events occurring during 2020–2025 by calendar year. Year-over-year growth rates were calculated as the percentage change from the preceding year. Complication rates (mortality, bleeding, perforation, infection, migration) were calculated as proportions of total events within each procedural indication category, using the complete 1775-event dataset. Given the passive surveillance nature of MAUDE and the absence of denominator data (total AXIOS procedures performed), true procedure-based incidence rates could not be calculated.[29,30] Therefore, all reported rates represent proportions of adverse events within the analyzed cohort rather than population-based complication rates.[22,31] Comparative analyses between indications were descriptive without formal statistical testing, as MAUDE data limitations preclude adjustment for confounding variables including patient selection, disease severity, operator experience, and institutional factors.[22,29,30,32,33] All analyses were performed using Python version 3.11 (Python Software Foundation, Wilmington, DE). Data processing and manipulation were conducted using pandas (version 2.0).[34] Visualizations were generated using matplotlib (version 3.7). Numerical computations were performed using NumPy (version 1.24).[34] This study utilized publicly available deidentified data and did not require institutional review board approval.[35]

Results

Overall Adverse Event Trends and Temporal Patterns

The analysis identified 1775 unique AXIOS adverse event reports submitted to the FDA MAUDE database during 2020–2025 (**Table 1**). Of these, 1667 had event dates within the study window, while the remaining 108 (6.1%) had event dates prior to 2020 but were reported during the study period. Annual reports increased from 144 events in 2020 to 478 events in 2025—an overall 232% increase (**Fig. 1**)—with the steepest year-over-year growth occurring between 2023 and 2024 (242–411 events, +69.8%). Event dates in the 2025 dataset extended through December 10, 2025, capturing approximately 94% of the calendar year.

Events were categorized by the FDA Event Type field as injury (52.8%, n = 937), malfunction (44.1%, n = 783), or death (3.0%, n = 54). A broader mortality definition—encompassing the FDA "Death" event type together with Patient Problem codes for multiple organ failure and cardiac arrest and narrative-confirmed deaths—identified 65 fatal events. The most frequent Patient Problem code was "No Clinical Signs, Symptoms or Conditions," recorded in 1305 reports (73.5%), indicating that the database is dominated by device-level events without documented clinical sequelae.

Table 1 Overall characteristics of Lumen-Apposing metal stent adverse events (n = 1775).

Characteristic	N	Percentage (%)
Total adverse events	1775	100
Year of event (2020–2025)		
2020	144	8.1
2021	172	9.7
2022	220	12.4
2023	242	13.6
2024	411	23.2
2025*	478	26.9
Events occurring 2020–2025†	1667	93.9
Procedural indication		
Pancreatic/WOPN	820	46.2
Biliary drainage	633	35.7
Gastroenterostomy	169	9.5
Other fluid collection/abscess	21	1.2
Not specified	132	7.4
FDA event classification		
Injury	937	52.8
Malfunction	783	44.1
Death	54	3.0
Not specified	1	0.1

© 2026. The Author(s).

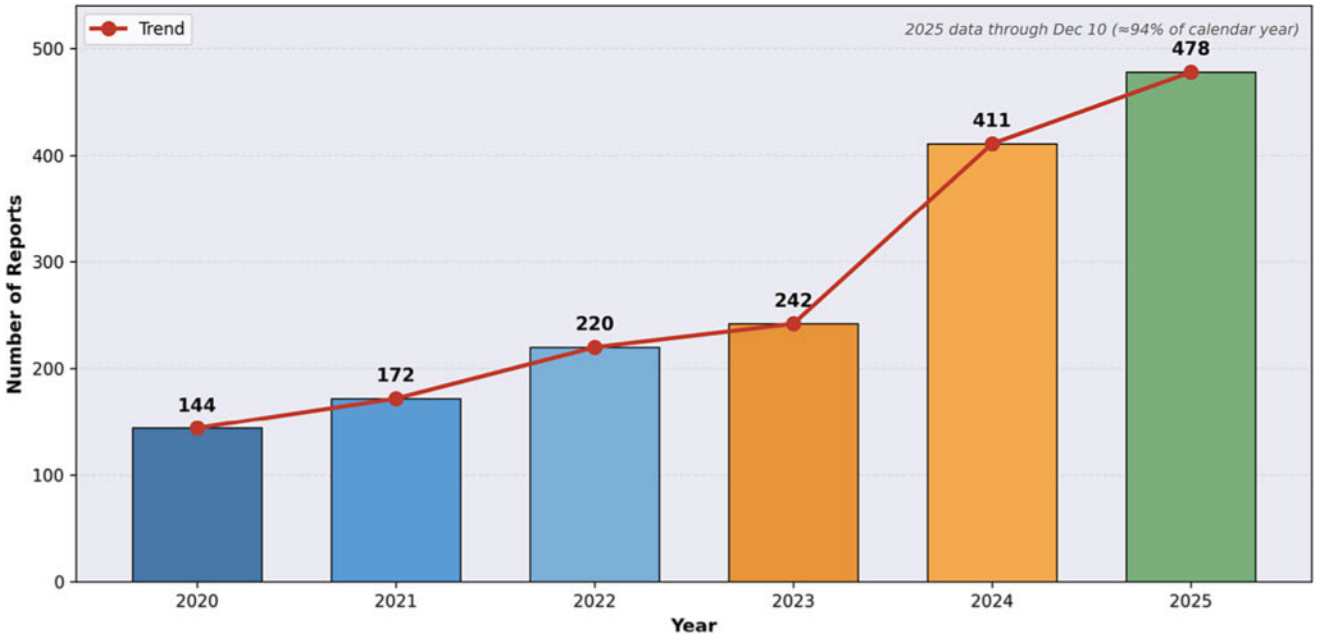


Fig. 1 Annual Adverse Event Reports for the Lumen-Apposing Metal Stent System (2020–2025). Bar chart displays annual adverse event counts, demonstrating an approximately 232% increase from 144 reports in 2020 to 478 in 2025. The trend line indicates sustained year-over-year growth across the entire study period. Counts reflect the 1667 reports with event dates during 2020–2025; the 2025 dataset includes events through December 10, 2025, representing approximately 94% of the calendar year. Value labels above each bar indicate exact annual counts.

Distribution by Procedural Indication

Pancreatic pseudocyst or walled-off pancreatic necrosis drainage was the most frequently reported indication, accounting for 46.2% (*n* = 820) of adverse events (**Table 1**). Biliary drainage—combining EUS-guided malignant biliary drainage and EUS-guided gallbladder drainage—comprised 35.7% (*n* = 633), and gastroenterostomy for gastric outlet obstruction accounted for 9.5% (*n* = 169). A further 1.2% (*n* = 21) of reports involved off-label drainage of other fluid collections or abscesses, and 7.4% (*n* = 132) lacked sufficient narrative detail to assign a procedural indication, predominantly predeployment or off-table device malfunctions (**Table 1**). Temporal analysis demonstrated a sustained, uninterrupted year-over-year increase in biliary drainage reports throughout the study period, rising from 28 events in 2020 to 218 in 2025; reports for the other major indications also increased over the period but with less consistent year-to-year trajectories (**Fig. 2**).

Adverse Outcomes by Procedural Indication

The patterns of severe adverse events differed substantially by procedural indication (**Table 2**). Among the 65 procedure-related mortality reports, biliary drainage accounted for 25 events (38.5%), gastroenterostomy for 20 (30.8%), and pancreatic drainage for 19 (29.2%). Of the 81 reports of procedure-related perforation, biliary drainage contributed 40 (49.4%), pancreatic drainage 30 (37.0%), and gastroenterostomy 11 (13.6%). Stent migration was distributed similarly between biliary drainage (42 events, 44.2%) and pancreatic drainage (40 events, 42.1%), with gastroenterostomy contributing 7 events (7.4%). Bleeding and infectious complications were concentrated in pancreatic and biliary drainage, reflecting their larger report volumes (bleeding: 46 [54.8%] pancreatic drainage and 22 [26.2%] biliary drainage; infection: 12 [40.0%] pancreatic drainage and 9 [30.0%] biliary drainage, respectively).

Expressed as a proportion of reports within each indication, gastroenterostomy (*n* = 169) carried the highest burden of serious primary adverse events. Mortality was the primary event in 11.8% of gastroenterostomy reports, compared with 3.9% for biliary drainage and 2.3% for pancreatic drainage; the corresponding figures were 6.5%, 6.3%, and 3.7% for perforation, and 4.1%, 1.4%, and 1.5% for infection. This pattern indicates that although gastroenterostomy represents a small share of total reports, it is disproportionately weighted toward the most severe outcomes.

Patient Adverse Events

Patient adverse events demonstrated distinct patterns and temporal trends (**Figs. 3** and **4A**). Hemorrhage and bleeding represented the most common patient complication, occurring in 7.9% (140/1775) of reports (**Fig. 4A**); annual counts increased from 11 events in 2020 to a peak of 26 in 2024 (**Fig. 3**). Perforation occurred in 5.3% (94/1775) of reports, increasing from 5 events in 2020 to 23 in 2025—an approximately fourfold rise over the study period (**Fig. 3**). Pain was documented in 3.4% (60/1775) of reports, fever in 1.7% (30/1775), and sepsis or septic shock in 1.2% (22/1775) (**Fig. 4A**).

Death or cardiac arrest was explicitly recorded in the Patient Problem field in only 0.2% (3/1775) of reports—far lower than

© 2026. The Author(s).

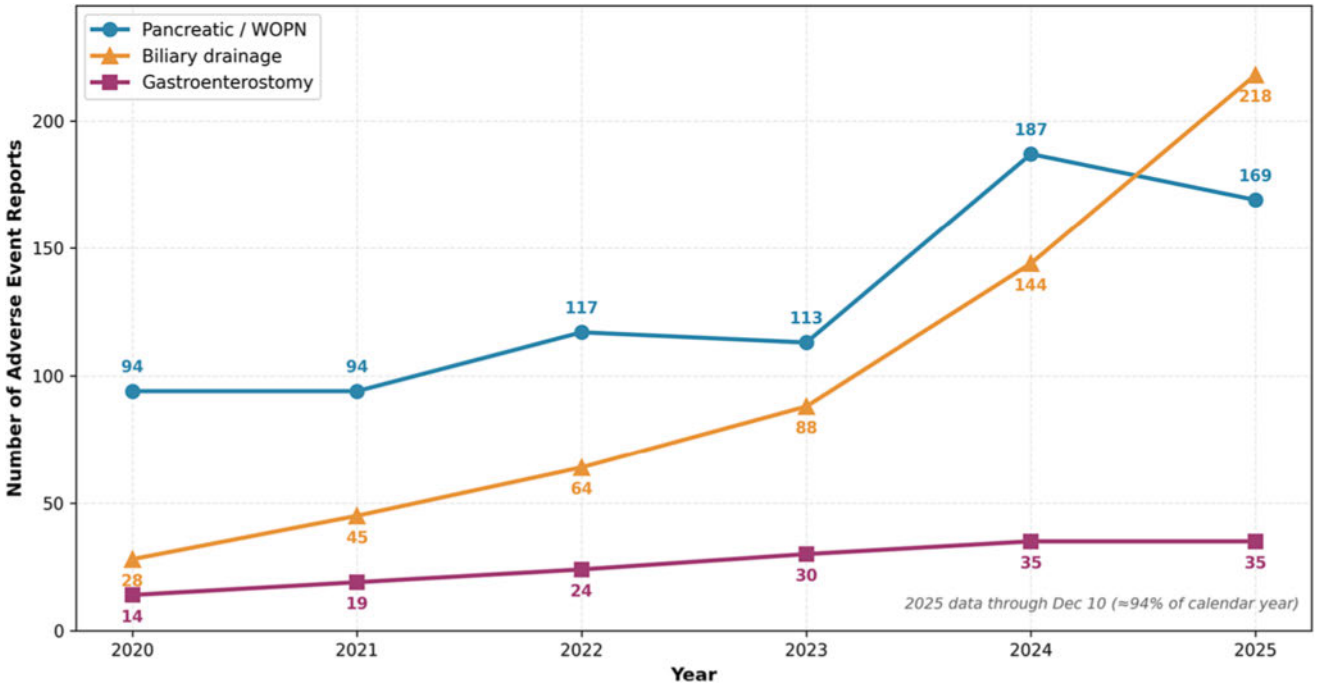


Fig. 2 Temporal Trends in Adverse Events by Procedural Indication (2020–2025). Annual adverse event reports for the three principal procedural indications among the 1667 reports with event dates during 2020–2025. Biliary drainage (combining EUS-guided malignant biliary drainage and gallbladder drainage) showed the steepest and most sustained increase, rising from 28 reports in 2020 to 218 in 2025 and surpassing pancreatic drainage in 2025. Pancreatic/WOPN drainage increased from 94 to 169 reports with year-to-year fluctuation, and gastroenterostomy increased modestly from 14 to 35 reports. The 2025 dataset includes events through December 10, 2025 (≈94% of the calendar year). Data labels indicate exact annual counts. Values represent counts of adverse event reports, not event rates; MAUDE provides no procedural denominator, so between-indication differences in trajectory reflect reporting volume and cannot be interpreted as differences in procedural risk.

Table 2 Adverse outcomes and complications by procedural indication (*n* = 1775).

Adverse event	Pancreatic/WOPN‡	Biliary drainage§	GOO/EUS-GE¶	Other fluid collection/abscess	Unknown/ not specified	TOTAL
Mortality	19 (2.3%)	25 (3.9%)	20 (11.8%)	0 (0.0%)	1 (0.8%)	65 (3.7%)
Perforation	30 (3.7%)	40 (6.3%)	11 (6.5%)	0 (0.0%)	0 (0.0%)	81 (4.6%)
Bleeding	46 (5.6%)	22 (3.5%)	11 (6.5%)	2 (9.5%)	3 (2.3%)	84 (4.7%)
Infection	12 (1.5%)	9 (1.4%)	7 (4.1%)	1 (4.8%)	1 (0.8%)	30 (1.7%)
Migration	40 (4.9%)	42 (6.6%)	7 (4.1%)	2 (9.5%)	4 (3.0%)	95 (5.4%)
Other AE	673 (82.1%)	495 (78.2%)	113 (66.9%)	16 (76.2%)	123 (93.2%)	1420 (80.0%)
TOTAL	**820 (100.0%)**	**633 (100.0%)**	**169 (100.0%)**	**21 (100.0%)**	**132 (100.0%)**	**1775 (100.0%)**

the 3.7% (65/1775) mortality identified through comprehensive narrative text and multifield analysis. This discrepancy reflects incomplete Patient Problem field completion and underscores the importance of structured narrative review in MAUDE-based adverse event surveillance.

Device-Related Problems

Positioning and malpositioning issues represented the predominant device problem, occurring in 59.0% (1047/1775) of reports (**Fig. 4B**). This composite category combined the MAUDE codes Positioning Problem (*n* = 424), Activation, Positioning or Separation Problem (*n* = 401), Positioning Failure (*n* = 256), and Difficult or Delayed Positioning (*n* = 76), reflecting difficulty achieving appropriate stent position, inadequate flange apposition, and suboptimal anastomotic alignment. Distal flange activation failures (MAUDE code Activation Failure) were the second most common device problem, affecting 19.4% (344/1775) of reports (**Fig. 4B**) and representing failure of the electrocautery system to deploy the distal flange during initial deployment. This category showed the most pronounced temporal escalation of any device problem, rising approximately 11-fold from 13 reports in 2020 to 145 in 2025 (**Fig. 5**).

© 2026. The Author(s).

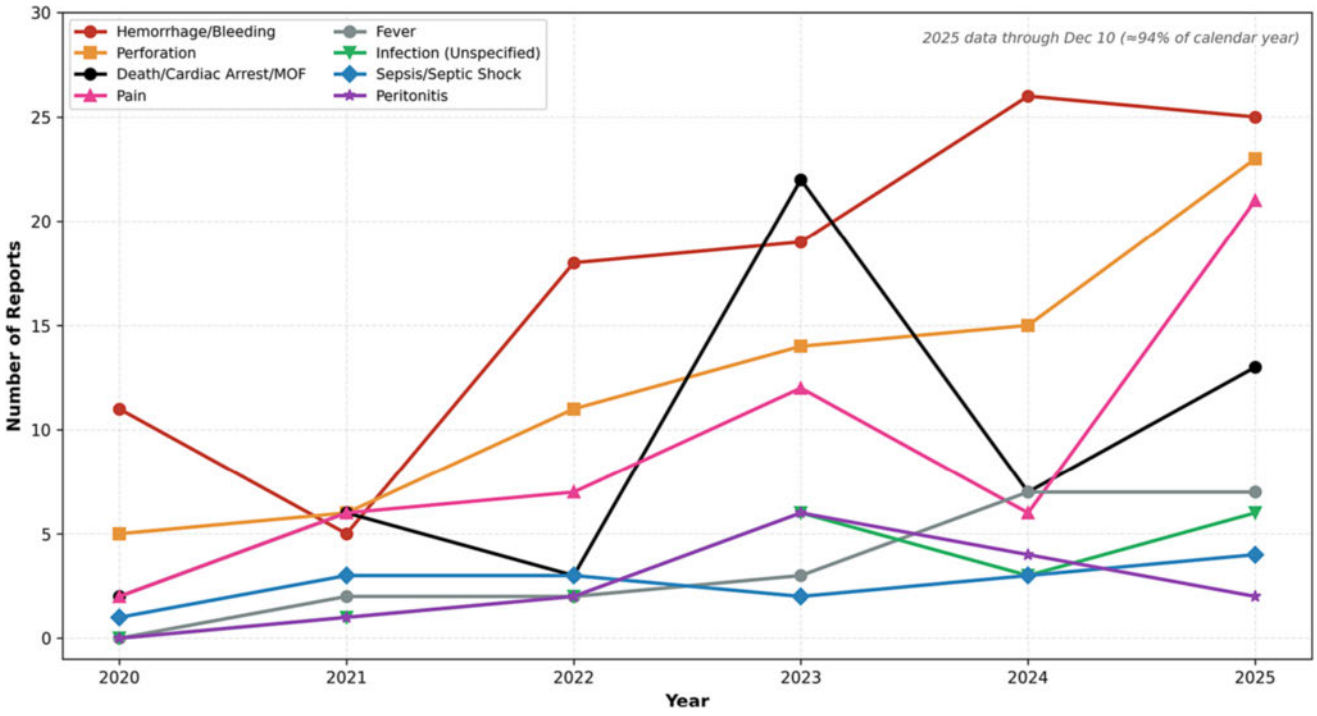


Fig. 3 Patient Adverse Event Trends by Year (2020–2025). Multiline graph showing the temporal evolution of eight patient adverse event categories among reports submitted during the study period. Hemorrhage/bleeding was the most frequently reported event in most years, rising from 11 reports in 2020 to a peak of 26 in 2024. Perforation increased overall from 5 reports in 2020 to 23 in 2025. Death/cardiac arrest/multiple organ failure showed a variable year-to-year pattern, including a peak of 22 reports in 2023. Pain, fever, infection, sepsis, and peritonitis were reported at lower frequencies throughout. The 2025 dataset includes events through December 10, 2025 (≈94% of the calendar year). Categories are non-mutually exclusive.

Proximal flange detachment (MAUDE code Detachment of Device or Device Component) occurred in 4.5% (79/1775) of reports (**Fig. 4B**), encompassing premature proximal flange release, detachment during or after deployment, and inadequate proximal apposition. Distal flange activation failures were thus approximately four times more frequent than proximal flange detachment, a disparity consistent with the greater technical complexity of distal flange deployment, which occurs without direct endoscopic visualization. Stent migration was documented as a device problem in 7.3% (129/1775) of reports, with annual counts ranging from 10 to 22 and no clear monotonic trend (**Figs. 4B** and **5**). Material integrity problems—combining the MAUDE codes Material Integrity Problem (*n* = 54), Material Deformation (*n* = 44), and Material Separation (*n* = 12)—occurred in 6.0% (107/1775) of reports, whereas stent breakage was documented in 6.4% (113/1775) and premature activation in 5.2% (92/1775) (**Figs. 4B** and **5**).

Stent Characteristics and Data Quality

Stent size was the most prominent data-quality gap. MAUDE adverse event reports do not include a structured device-size field, so stent dimensions were recoverable only from free-text narrative descriptions. Explicit stent dimensions were documented in just 236 of 1775 reports (13.3%); the remaining 1539 (86.7%) contained no extractable size information. This severe under-documentation precluded meaningful size-stratified outcome analysis and represents an important limitation of MAUDE for postmarket surveillance of devices, such as AXIOS, that are marketed in multiple dimensional configurations.

Discussion

This analysis of 1775 AXIOS adverse event reports submitted to MAUDE between 2020 and 2025 produced three findings that matter for practice. Annual reporting more than tripled, the risk profile differed sharply by procedural indication, and reports of distal flange activation failure increased roughly 11-fold—a climb that coincided, almost to the month, with a manufacturer recall. Taken together, these observations show both what passive surveillance can do and where it falls short.

The rise in reports is best understood as wider use of the device combined with better reporting, not as a device that is becoming less safe. AXIOS use has expanded well beyond drainage of pancreatic fluid collections into biliary, gallbladder, and gastroenteric applications, and report volume has followed that expansion.[24,25,36] Because MAUDE records events but not the number of procedures performed, this growth reflects changing practice rather than changing risk per procedure.

The indications also diverge in their reporting trajectories, and this divergence warrants care in interpretation. Biliary drainage reports increased without interruption across the study period,

© 2026. The Author(s).

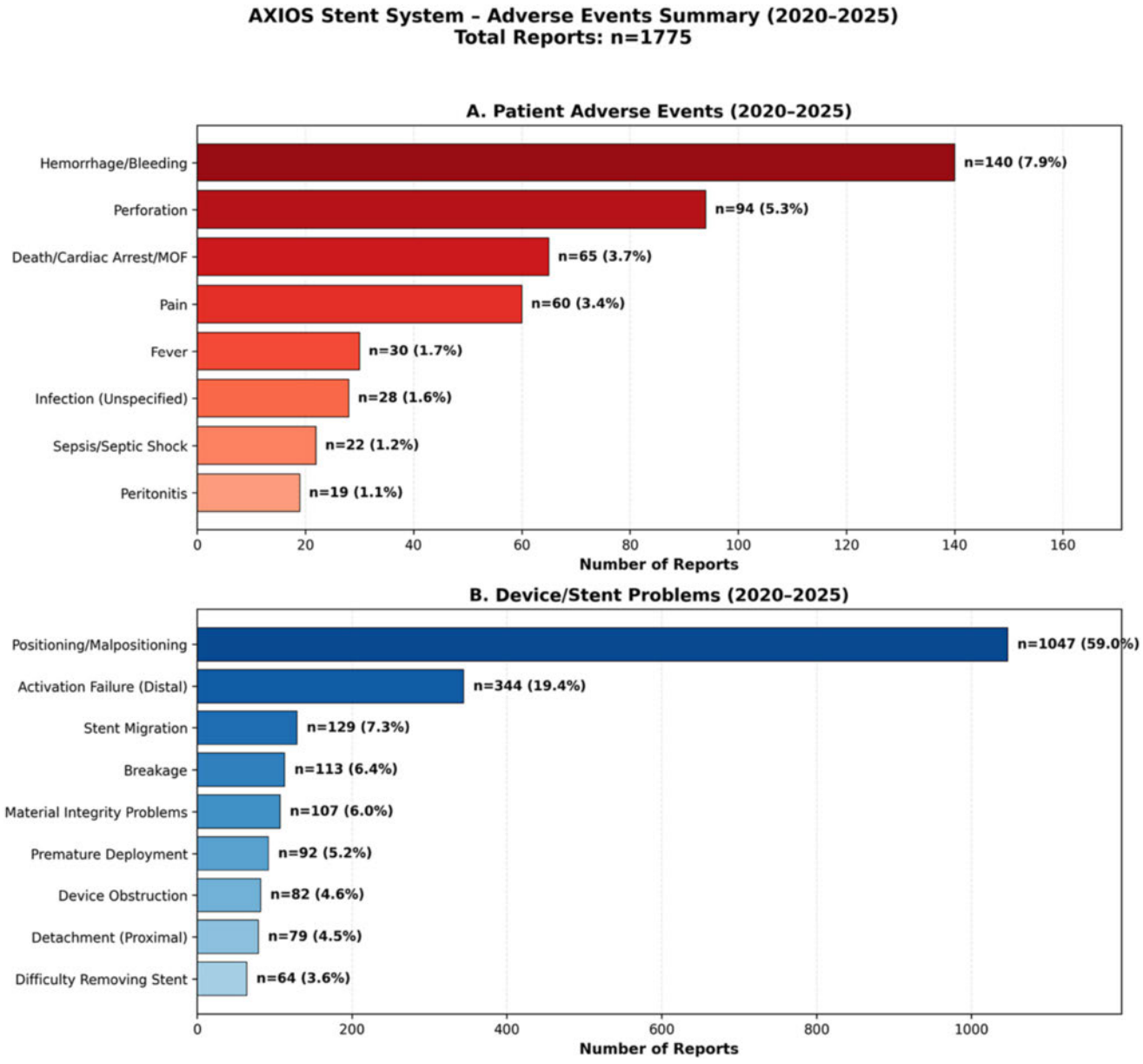


Fig. 4 Summary of Patient Adverse Events and Device Problems (2020–2025). Horizontal bar charts displaying ranked frequencies of (A) eight patient adverse event categories and (B) nine device/stent problem categories, with exact counts and percentages of total reports (*n* = 1775). Among patient events, hemorrhage/bleeding was most frequent (7.9%), followed by perforation (5.3%). Among device problems, positioning/malpositioning predominated (59.0%), and distal flange activation failures (19.4%) substantially exceeded proximal flange detachment (4.5%). Categories are non-mutually exclusive; a single report may contribute to more than one category.

whereas gastroenterostomy reports remained comparatively flat. Because the figures display report counts rather than rates and the MAUDE database provides no procedural denominator, this contrast cannot be attributed to differences in safety. The most parsimonious explanation is differential growth in procedural volume: biliary and gallbladder drainage have expanded most rapidly of the three indications and have diffused well beyond tertiary centers, consistent with a rapidly enlarging denominator, while EUS-GE remains a lower-volume procedure concentrated in fewer high-volume centers and accounted for only 9.5% of reports. A stable count against a slowly growing denominator is compatible with either a stable or a falling event rate, and the two cannot be distinguished here. The stability should not, however, be read as reassurance: gastroenterostomy carries the highest within-indication proportion of mortality, perforation, and infection in the cohort, so the flat trajectory reflects report volume rather than severity.

The differences between indications are the most useful finding here, and they have a clear mechanistic explanation. Measured as a proportion of reports within each indication, gastroenterostomy carried the heaviest burden of serious events—mortality 11.8%, perforation 6.5%, and infection 4.1%—well

© 2026. The Author(s).

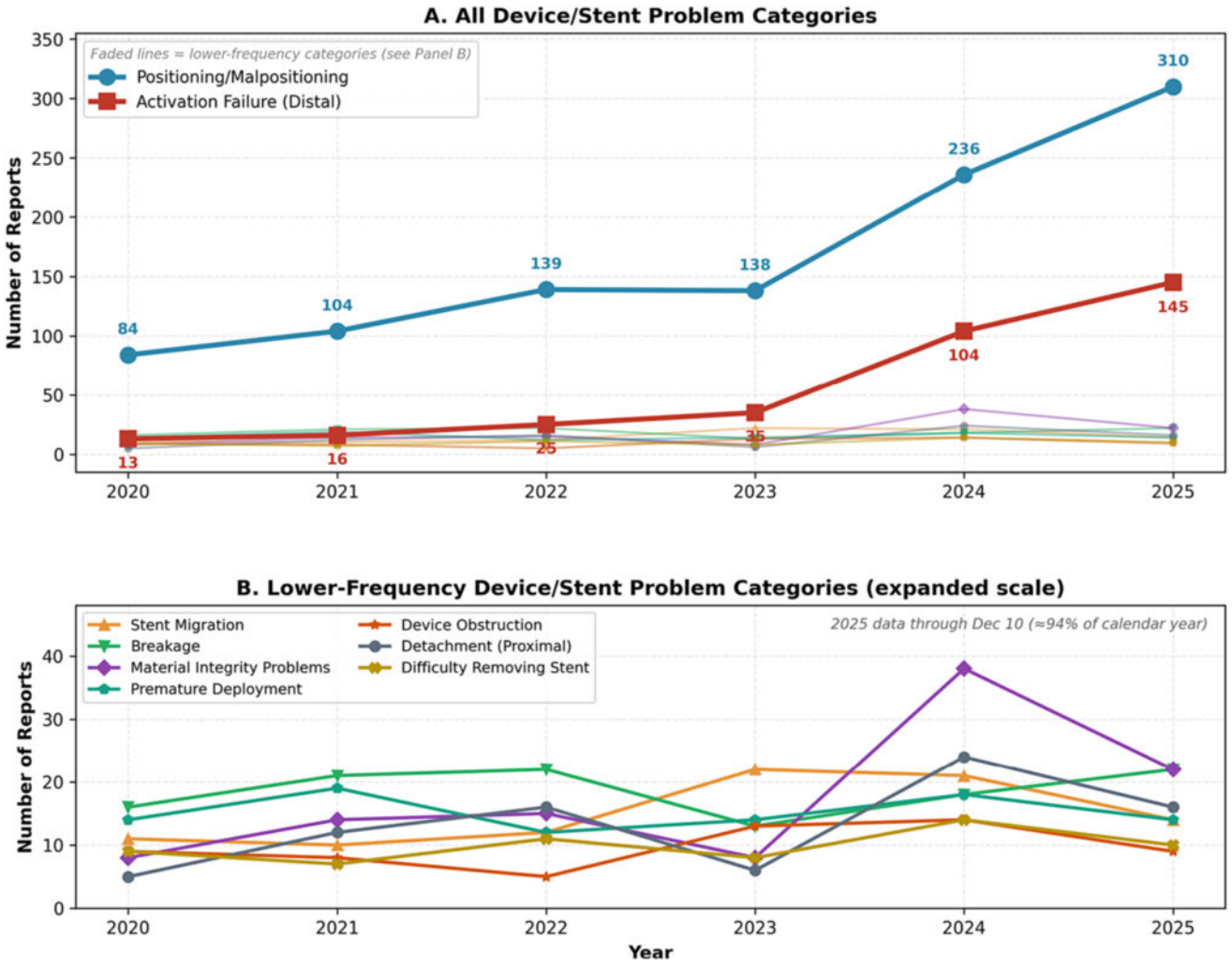


Fig. 5 Device/Stent Problem Trends by Year (2020–2025). (**A**) Annual frequencies of all 9 device problem categories; positioning/malpositioning (84–310 reports) and distal flange activation failures (13–145 reports, an approximately 11-fold increase) are shown as emphasized lines, with the seven lower-frequency categories displayed faded for context. (**B**) The same seven lower-frequency categories shown on an expanded scale for legibility. Proximal flange detachment remained substantially lower than distal activation failure throughout, consistent with proximal flange deployment occurring under direct endoscopic visualization. The 2025 dataset includes events through December 10, 2025 (≈94% of the calendar year). Categories are non-mutually exclusive.

above biliary drainage (3.9%, 6.3%, 1.4%) and pancreatic drainage (2.3%, 3.7%, 1.5%). The gradient makes intuitive sense: a misdeployed stent at a free gastroenteric anastomosis spills enteric contents into the peritoneum, whereas a misdeployed stent during pancreatic drainage decompresses into a contained, walled-off collection. The same logic explains why gastroenterostomy, despite making up only a small share of reports, repeatedly emerges as the highest-acuity indication. The one exception is migration, which was most frequent not in gastroenterostomy but in biliary drainage (6.6%)—likely the result of peristaltic shear at the cholecystoenteric and choledochoenteric anastomoses and weaker tissue ingrowth across noninflamed walls. Two established measures—larger-diameter stents and prophylactic fixation with endoscopic suturing or over-the-scope clips—have reduced migration in comparative studies and deserve indication-specific consideration.[37–40]

These proportions should not be read as procedural complication rates. MAUDE overrepresents severe outcomes and lacks a procedure-volume denominator, so absolute figures are best read as proportions of reported events rather than procedural risk. Reported perforation proportions for gastroenterostomy illustrate this: the nonexclusive estimate (10.7%) closely matches a prior MAUDE analysis (10.4%) and exceeds prospective series (2–5%),[23] whereas the primary-event estimate used here (6.5%) is lower by virtue of the mutually exclusive classification. The two methods differ in magnitude but not in direction—across all surveillance modes, gastroenterostomy emerges as the highest-acuity indication, and that ranking, rather than any single rate, should guide practice.

On the device itself, the defining signal is the contrast between the two anchor flanges. Distal flange activation failures (19.4%) outnumbered proximal detachment (4.5%) by roughly

© 2026. The Author(s).

four to one, a difference that follows directly from how the device deploys. The distal flange is released blindly through tissue, leaving it exposed to electrocautery malfunction, poor apposition, and premature activation, while the proximal flange deploys under direct endoscopic vision.[3,27,41–43] More telling is the trajectory: distal activation failures increased from 13 reports in 2020 to 145 in 2025, an 11-fold increase that far outpaced the roughly threefold growth in overall reporting. In December 2025, Boston Scientific issued an urgent field safety notice for specific AXIOS configurations, citing deployment failures.[41] That an independently derived MAUDE signal converged with manufacturer action is the clearest evidence in this dataset of what surveillance can accomplish.

A second safety consideration warrants mention. AXIOS is FDA approved for transgastric or transduodenal drainage of pancreatic pseudocysts and walled-off necrosis, and for EUS-guided gallbladder drainage in nonoperative surgical candidates; its use for EUS-GE in gastric outlet obstruction remains off-label. In parallel, the dual-balloon enteroclysis catheter (NAJA, Chess Medical, Montreal, Canada) has been adopted to facilitate EUS-GE by distending an isolated small-bowel segment prior to LAMS deployment, and early experience suggests the technique may reduce procedural adverse events through improved target visualization and stable apposition.[44] It should be noted, however, that NAJA is FDA-cleared for endoscopic evaluation of the small intestine, not for the creation of enteric anastomoses, so its use in EUS-GE is itself off-label. These dual off-label considerations underscore the importance of careful patient selection, transparent informed consent, and continued development of dedicated devices and approval pathways for non-PFC LAMS indications.

These findings carry several practical implications. Patients considered for gastroenterostomy should be counseled explicitly about elevated mortality and perforation risk, and surgical gastrojejunostomy or enteral stenting should be genuinely weighed when life expectancy and oncologic context allow. Patients undergoing biliary drainage should be counseled specifically about migration. Pancreatic drainage carries the most favorable mortality profile of the three, with bleeding as its main procedural concern. For endoscopists, distal flange deployment is the critical step—the largest category of device failure and the fastest growing. One factor this dataset cannot measure, but that almost certainly shapes these numbers, is operator experience. Successful LAMS deployment depends on advanced EUS skill, and part of the rise in reported complications may simply reflect the technique spreading beyond high-volume expert centers into less experienced hands. MAUDE records the event but never the endoscopist, so this influence is invisible in the data even as it likely contributes to it. As LAMS use continues to diffuse into broader practice, structured proctorship—together with defined competency thresholds and standardized curricula—is likely to matter more than didactic instruction alone, although the present data cannot evaluate this directly. A recent survey of advanced endoscopy fellowship programs documented marked variability in LAMS training exposure and competency assessment, supporting the case for more standardized curricula as these techniques continue to disseminate.[45]

The strengths of this study are its scale and detail: the largest AXIOS-specific MAUDE cohort reported to date, six continuous years of data, and indication-level profiling drawn from systematic review of report narratives. Its limitations are inherent to MAUDE. Passive surveillance captures only a small and biased fraction of true events, cannot establish causality, and provides no procedure denominator.[22,46,47] Structured data fields were often uninformative—"No Clinical Signs" filled 73.5% of the Patient Problem field, and stent dimensions could be recovered from narrative text in only 13% of reports—which required labor-intensive manual review and ruled out size-stratified analysis. The rise in reports also blends genuine safety signals with growth in use and improved reporting, and reporting lag right-censors the most recent years: 10–23% of events from 2020 to 2024 were not logged until a later calendar year, so 2025 counts are necessarily incomplete and the temporal increases reported here are conservative estimates (**Supplementary Fig. 2** [available in online version only]). These constraints define what the analysis can claim: relative, hypothesis-generating signals, not population incidence. Three further limitations warrant mention. First, the biliary drainage category pools EUS-guided drainage of the biliary tree with EUS-guided gallbladder drainage. These are distinct procedures with different access windows and plausibly different risk profiles, and separating them would be clinically valuable, but we were unable to do so reliably: gallbladder-related terms appear in approximately one quarter of narratives, yet in the majority of these, the only mention lies within the manufacturer's standard Directions-for-Use text, which enumerates all cleared indications irrespective of the procedure performed. Keyword-based assignment would therefore have produced substantial misclassification. Second, MAUDE does not permit determination of the interval from LAMS placement to death: the database records individual adverse event reports rather than a followed cohort, patients are neither censored nor tracked longitudinally after a reported event, and no procedure-date field exists, so temporal attribution of mortality to the index procedure is not possible. Third, 10 pairs of reports shared identical narrative text under distinct report numbers; most reflect established MAUDE conventions, namely separate reports filed for each device used in a single procedure and literature-derived reports sharing a common source narrative, but because manufacturer narratives are templated a small residue of true duplication cannot be excluded. At fewer than 1% of records, any such residue is too small to alter the reported proportions.

In summary, AXIOS adverse events show distinct, indication-specific patterns. Gastroenterostomy is the highest-acuity indication for mortality, perforation, and infection; biliary drainage carries the greatest migration burden; pancreatic drainage is comparatively the safest. The 11-fold rise in distal flange activation failures, confirmed by a concurrent manufacturer recall, shows that MAUDE—for all its limitations—can detect clinically meaningful device signals before they are formally characterized. Confirming and quantifying these signals will require prospective multicenter registries with complete case ascertainment, standardized outcome definitions, and mandatory device characterization—the steps needed to turn the relative signals reported here into the absolute, denominator-based risk

© 2026. The Author(s).

estimates that truly evidence-based device selection requires.[46–53] Such registries should record the target organ explicitly, permitting the separation of gallbladder from biliary tree drainage that passive surveillance narratives cannot support, and should record the date of index placement, permitting attribution of mortality to a defined postprocedural interval. Finally, because the December 2025 field safety notice postdates this data window, its effect on reporting patterns could not be assessed; reinterrogation of MAUDE after a sufficient postnotice interval would permit direct evaluation of whether the recall altered the frequency or character of reported deployment failures.

Key Messages

1. Among LAMS indications, gastroenterostomy carries the highest within-indication burden of serious adverse events—mortality (11.8%), perforation (6.5%), and infection (4.1%)—substantially exceeding biliary and pancreatic drainage, underscoring the need for careful patient selection and explicit preprocedure counseling.
2. Distal flange activation failures (19.4%) were reported approximately four times more often than proximal flange detachment (4.5%), reflecting the technical difficulty of deploying the distal flange without direct endoscopic visualization, with implications for operator training and device refinement.
3. MAUDE surveillance can detect real-world safety signals: distal flange activation failures increased roughly 11-fold over the study period, a trend that coincided with a December 2025 Boston Scientific field safety notice citing deployment failures.
4. Operator experience is not captured in MAUDE and could not be assessed here; whether the approximately 232% rise in adverse event reporting between 2020 and 2025 partly reflects diffusion of these techniques beyond expert centers is a hypothesis this dataset can generate but cannot test.

Author Affiliations

1 Gastroenterology, University of Illinois Chicago College of Medicine at Peoria, Peoria, Illinois, United States
2 Center for Interventional Endoscopy, AdventHealth Orlando, Orlando, Florida, United States
3 Gastroenterology, Brigham and Women's Hospital, Boston, Massachusetts, United States
4 Medicine, University of Central Florida, Orlando, Florida, United States

Statements and Additional Information

Conflict of Interest N.D.C. is a consultant for Boston Scientific and Olympus. M.A.A. is a consultant for Cook Medical, Boston Scientific, and Olympus. D.Y. is a consultant for Micro-Tech, Medtronic, Olympus, Fujifilm, 3-D Matrix, ERBE, and Aspero Medical. M.K.H. is a consultant for Boston Scientific, Olympus, and Micro-Tech. The remaining authors disclosed no financial relationships relevant to this publication.

Declaration of GenAI Use Generative artificial intelligence (Claude, Anthropic) was used in the preparation of this manuscript to assist with data processing, analysis code development, and drafting and language editing of the text. Figures and tables are data visualizations derived from statistical analysis using standard visualization libraries; no generative AI was used to create images. All analytic outputs and findings were reviewed and verified by the authors, and all interpretations and conclusions are those of the authors. The authors take full responsibility for the integrity of the data, the accuracy of the analysis, and the content of this manuscript.

Data Availability Statement The data analyzed in this study are publicly available from the US FDA MAUDE database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm). Derived analytic datasets are available from the corresponding author upon reasonable request.

Contributors' Statement I.V.: Methodology, Writing - original draft, Writing - review & editing. M.K.H.: Project administration, Supervision. H.G.: Methodology, Project administration, Writing - original draft, Writing - review & editing. D.Y.: Project administration, Writing - original draft. D.J.: Project administration, Resources. N.C.: Formal analysis, Supervision. M.H.: Investigation, Writing - review & editing. R.A.: Writing - review & editing. A.M.: Methodology, Writing - original draft, Writing - review & editing. Z.K.: Methodology, Writing - original draft, Writing - review & editing. C.-R.B.: Data curation, Methodology, Writing - review & editing. M.A.A.: Conceptualization, Methodology, Software, Writing - original draft.

© 2026. The Author(s). This is an open access article published by Thieme under the terms of the Creative Commons Attribution License, permitting unrestricted use, distribution, and reproduction so long as the original work is properly cited. (https://creativecommons.org/licenses/by/4.0/).

Note This study was previous presented at DDW 2026 Chicago Poster presentation.

Supplementary Material is available online at https://doi.org/10.1055/a-2979-6046

References

1 Ang TL, Khor CJL. Interventional endosonography comes of age: an update on endoscopic ultrasonography-guided drainage and anastomosis procedures. Singapore Med J 2025;66(08):420–425
2 Dorrell R, Pawa S, Pawa R. Endoscopic Management of Pancreatic Fluid Collections. J Clin Med 202110 (02)
3 Bang JY, Varadarajulu S. Lumen-apposing metal stents for endoscopic ultrasonography-guided interventions. Dig Endosc 2019;31(06):619–626
4 Sharma P, McCarty TR, Chhoda A, et al. Alternative uses of lumen apposing metal stents. World J Gastroenterol 2020;26(21):2715–2728
5 Binmoeller KF, Shah J. A novel lumen-apposing stent for transluminal drainage of nonadherent extraintestinal fluid collections. Endoscopy 2011;43(04):337–342
6 Itoi T, Binmoeller KF, Shah J, et al. Clinical evaluation of a novel lumen-apposing metal stent for endosonography-guided pancreatic pseudocyst and gallbladder drainage (with videos). Gastrointest Endosc 2012;75(04):870–876
7 Rinninella E, Kunda R, Dollhopf M, et al. EUS-guided drainage of pancreatic fluid collections using a novel lumen-apposing metal stent on an electrocautery-enhanced delivery system: a large retrospective study (with video). Gastrointest Endosc 2015;82(06):1039–1046
8 Baron TH, DiMaio CJ, Wang AY, Morgan KA. American Gastroenterological Association clinical practice update: management of pancreatic necrosis. Gastroenterology 2020;158(01):67–75 e1
9 Suresh Kumar VC, Singh S, Moond V, et al. Safety and efficacy of lumen-apposing metal stents for endoscopic ultrasound-guided drainage of pancreatic fluid collections: a systematic review and meta-analysis. Endoscopy 2025;57(03):282–290
10 Jain H, Dey D, Odat RM, et al. Endoscopic ultrasound-guided gastroenterostomy versus duodenal stenting for gastric outlet obstruction: a systematic review, meta-analysis, and meta-regression. Medicine 2024;103(40):e39948
11 Vanella G, Dell'Anna G, Capurso G, et al. EUS-guided gastroenterostomy for management of malignant gastric outlet obstruction: a prospective cohort study with matched comparison with enteral stenting. Gastrointest Endosc 2023;98(03):337–47 e5
12 American Society for Gastrointestinal Endoscopy Standards of Practice CommitteeMarya NB, Pawa S, Thiruvengadam NR, et al. American Society for Gastrointestinal Endoscopy guideline on the role of therapeutic EUS in the management of biliary tract disorders: methodology and review of evidence. Gastrointest Endosc 2024;100(06):e79–e135
13 Ginestet C, Sanglier F, Hummel V, et al. EUS-guided biliary drainage with electrocautery-enhanced lumen-apposing metal stent placement should replace PTBD after ERCP failure in patients with distal tumoral biliary obstruction: a large real-life study. Surg Endosc 2022;36(05):3365–3373
14 Rodrigues-Pinto E, Baron TH. Evaluation of the AXIOS stent for the treatment of pancreatic fluid collections. Expert Rev Med Devices 2016;13(09):793–805

15 Kadah A, Khoury T, Mari A, Mahamid M, Sbeit W. Lumen-apposing metal stents in interventional endoscopy: a state-of-the-art review with focus on technical and clinical successes and complications. Eur J Gastroenterol Hepatol 2020; 32(01):1–9

16 Patil R, Ona MA, Papafragkakis C, Anand S, Duddempudi S. Endoscopic ultrasound-guided placement of AXIOS stent for drainage of pancreatic fluid collections. Ann Gastroenterol 2016;29(02):168–173

17 Li JS, Tang J, Fang J, Li ZS, Liu F. Adverse events in endoscopic ultrasound-guided choledochoduodenostomy with lumen-apposing metal stents: a systematic review and meta-analysis. J Gastroenterol Hepatol 2024;39(09): 1769–1779

18 Hammad T, Khan MA, Alastal Y, et al. Efficacy and safety of lumen-apposing metal stents in management of pancreatic fluid collections: are they better than plastic stents? A systematic review and meta-analysis. Dig Dis Sci 2018;63(02): 289–301

19 Lang GD, Fritz C, Bhat T, et al. EUS-guided drainage of peripancreatic fluid collections with lumen-apposing metal stents and plastic double-pigtail stents: comparison of efficacy and adverse event rates. Gastrointest Endosc 2018; 87(01):150–157

20 Garcia-Alonso FJ, Sanchez-Ocana R, Penas-Herrero I, et al. Cumulative risks of stent migration and gastrointestinal bleeding in patients with lumen-apposing metal stents. Endoscopy 2018;50(04):386–395

21 Lyu Y, Li T, Wang B, Cheng Y, Chen L, Zhao S. Comparison between lumen-apposing metal stents and plastic stents in endoscopic ultrasound-guided drainage of pancreatic fluid collection: a meta-analysis and systematic review. Pancreas 2021;50(04):571–578

22 Tau N, Shepshelovich D. Assessment of data sources that support US Food and Drug Administration medical devices safety communications. JAMA Intern Med 2020;180(11):1420–1426

23 Ramai D, Facciorusso A, DeLuca M, Barakat M, Adler DG. Adverse events associated with AXIOS stents: insights from the manufacturer and user facility device experience database. Endosc Ultrasound 2022;11(03):231–236

24 Bhenswala P, Lakhana M, Gress FG, Andalib I. Novel uses of lumen-apposing metal stents: a review of the literature. J Clin Gastroenterol 2021;55(08): 641–651

25 Hindryckx P, Degroote H. Lumen-apposing metal stents for approved and off-label indications: a single-Centre experience. Surg Endosc 2021;35(11): 6013–6020

26 Choi JH, Kozarek RA, Larsen MC, et al. Effectiveness and safety of lumen-apposing metal stents in endoscopic interventions for off-label indications. Dig Dis Sci 2022;67(06):2327–2336

27 Stefanovic S, Degroote H, Hindryckx P. Reduction of Lams-related adverse events with accumulating experience in a large-volume tertiary referral center. J Clin Med 2023:12[3]

28 U.S. Food and Drug Administration. MAUDE — Manufacturer and User Facility Device Experience. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

29 Ziapour B, Zaepfel C, Iafrati MD, Suarez LB, Salehi P. A systematic review of the quality of cardiovascular surgery studies that extracted data from the MAUDE database. J Vasc Surg 2021;74(05):1708.e5–1720.e5

30 Sung VW, Tunitsky-Bitton E, Bradley CS, Ridgeway B. Assessing and adopting new medical devices for obstetric and gynecologic care. Obstet Gynecol 2020; 135(03):e160–e166

31 Batheja A, Bentan M, Coelho DH. Considerations for use of the MAUDE database in Otolaryngology-Head & Neck Surgery Research. Otolaryngol Head Neck Surg 2024;171(01):320–322

32 Davies C, Nieri CA, Sheyn A, Rangarajan S, Yawn RJ. The use and utility of Food and Drug Administration adverse event data from the manufacturer and user facility device experience database in otology: a systematic review. Otol Neurotol 2023;44(06):534–541

33 Liao TJ, Crosby L, Cross K, Chen M, Elespuru R. Medical device report analyses from MAUDE: device and patient outcomes, adverse events, and sex-based differential effects. Regul Toxicol Pharmacol 2024;149:105591

34 W. MK. Data structures for statistical computing in python. In: Proceedings of the 9th Python in Science Conference. Austin, TX, 2010

35 Danchev V, Min Y, Borghi J, Baiocchi M, Ioannidis JPA. Evaluation of data sharing after implementation of the International Committee of Medical Journal Editors Data Sharing Statement Requirement. JAMA Netw Open 2021;4(01): e2033972

36 Northup PG, Garcia-Pagan JC, Garcia-Tsao G, et al. Vascular liver disorders, portal vein thrombosis, and procedural bleeding in patients with liver disease: 2020 practice guidance by the American Association for the Study of Liver Diseases. Hepatology 2021;73(01):366–413

37 Shinn B, Boortalary T, Raijman I, et al. Maximizing success in single-session EUS-directed transgastric ERCP: a retrospective cohort study to identify predictive factors of stent migration. Gastrointest Endosc 2021;94(04):727–732

38 Bejjani M, Ghandour B, Subtil JC, et al. Clinical and technical outcomes of patients undergoing endoscopic ultrasound-guided gastroenterostomy using 20-mm vs. 15-mm lumen-apposing metal stents. Endoscopy 2022;54(07):680–687

39 Park KH, Lew D, Samaan J, et al. Comparison of no stent fixation, endoscopic suturing, and a novel over-the-scope clip for stent fixation in preventing migration of fully covered self-expanding metal stents: a retrospective comparative study (with video). Gastrointest Endosc 2022;96(05):771–779

40 Ngamruengphong S, Sharaiha RZ, Sethi A, et al. Endoscopic suturing for the prevention of stent migration in benign upper gastrointestinal conditions: a comparative multicenter study. Endoscopy 2016;48(09):802–808

41 Boston Scientific Corporation. Urgent field safety notice — urgent medical device recall. In: AXIOS Stent and Electrocautery Enhanced Delivery System. Reference 97507023-FA, SRN: US-MF-000004702 Marlborough (MA): Boston Scientific; 2025

42 Braden B, Hocke M, Selvaraj E, et al. Mishaps with EUS-guided lumen-apposing metal stents in therapeutic pancreatic EUS: management and prevention. Endosc Ultrasound 2023;12(05):393–401

43 Mishra G, Lennon AM, Pausawasdi N, Shami VM, Sharaiha RZ, Elmunzer BJ. Quality indicators for EUS. Am J Gastroenterol 2025;120(05):973–992

44 Chen YI, Menard C, Khashab M, et al. EUS-guided gastroenterostomy using a novel through-the-scope exchangeable dual-balloon enteroclysis catheter: a potentially secure and scalable approach. VideoGIE 2023;8(12):500–502

45 Xiao Y, Hayat M, Mohammed AS, et al. Status of training in the use of lumen-apposing metal stents for therapeutic endoscopic ultrasound during advanced endoscopy fellowship: a survey questionnaire. iGIE 2025;4(04):338–344.e3

46 Fabbri C, Coluccio C, Binda C, et al. Lumen-apposing metal stents: how far are we from standardization? An Italian survey. Endosc Ultrasound 2022;11(01):59–67

47 Gao Z, Lei W, Gao E, Bhatia S. Device-related patient outcomes for coronary stents: a MAUDE database analysis. Heliyon 2024;10(24):e40908

48 Bhatt DL, Drozda JP Jr, Shahian DM, et al. ACC/AHA/STS statement on the future of registries and the performance measurement Enterprise: a report of the American College of Cardiology/American Heart Association task force on performance measures and the society of thoracic surgeons. J Am Coll Cardiol 2015;66(20):2230–2245

49 Association of Cardiovascular Nursing and Allied Professions, Association for Acute CardioVascular Care, European Association of Percutaneous Cardiovascular Interventionset al. Data standards for acute coronary syndrome and percutaneous coronary intervention: the European unified registries for heart care evaluation and randomised trials (EuroHeart). Eur Heart J 2022;43(24):2269–2285

50 Bonow RO, O'Gara PT, Adams DH, et al. 2019 AATS/ACC/SCAI/STS expert consensus systems of care document: operator and institutional recommendations and requirements for Transcatheter mitral valve intervention. J Am Coll Cardiol 2020;76(01):96–117

51 Topol EJ. High-performance medicine: the convergence of human and artificial intelligence. Nat Med 2019;25(01):44–56

52 Kadakia KT, Beckman AL, Ross JS, Krumholz HM. Renewing the call for reforms to medical device safety — the case of penumbra. JAMA Intern Med 2022;182(01): 59–65

53 Cotton PB, Eisen GM, Aabakken L, et al. A lexicon for endoscopic adverse events: report of an ASGE workshop. Gastrointest Endosc 2010;71(03):446–454

© 2026. The Author(s).