



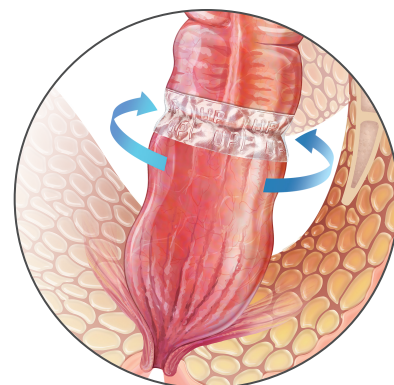
Retrospective multicenter study with AMNIOFIX[®] as a protective barrier after colonic anastomoses in complicated diverticulitis patients

Study Design:

Retrospective chart review of consecutive adults with a primary colectomy and complicated diverticulitis who received AMNIOFIX wrapped around the anastomosis site as a protective barrier after a colectomy without a protective ostomy between January 1, 2016, and June 30, 2024.

Methods:

- Evaluation of consecutive adult patients (≥18 years) who underwent left-sided colectomy without a protective stoma. In most cases (98.3%), pneumatic leak testing was performed to assess anastomotic integrity, and/or intraoperative Indocyanine Green (ICG) fluorescence angiography was used to assess colonic and rectal perfusion.
- **Primary endpoint:** Anastomotic leak incidence within 30 days of surgery. Anastomotic leak was defined to reflect real-world practice and align with published data and included reoperation (related to the anastomosis), reanastomosis, stenting, colostomy, drainage, or abscess within 30 days postop.
- **Secondary endpoint:** Reoperation, readmission, length of stay, and in-hospital mortality.



AMNIOFIX is a dehydrated human amnion/chorion membrane placental sheet allograft that provides a protective barrier and thereby supports the healing cascade.

Patient Demographics (n=178)

Mean Age Year: 60.5 (Range 48-67)	Sex: Male 80 (44.9%) / Female 98 (55.1%)	Mean BMI kg/m²: 28.8 (Range 25.6-34.4)
ASA Physical Status Classification: I: 2 (1.1%) / II: 101 (56.7%) / III: 74 (41.6%) / IV: 1 (0.6%)		
Colectomy Type (n, %): Sigmoid Colectomy: 166 (93.3%) / Low Anterior Resection: 10 (5.6%) / Extended Left Colectomy: 2 (1.1%)		
Indication: Complicated diverticulitis, 178 (100%)		
Laparoscopic: 115 (64.6%) / Laparoscopic Converted to Open: 2 (1.7%) / Robotic: 48 (27%) / Robotic Converted to Open: 5 (10.4%) / Open: 7 (3.9%)		

Results:

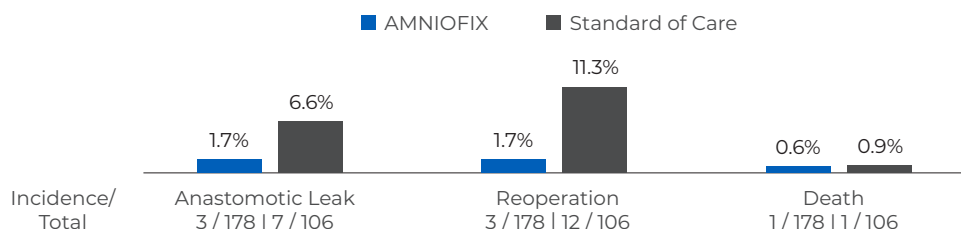
AMNIOFIX recipients had a low 30-day all-cause readmission (3.9%) and low anastomotic leak rate (1.7%). The leaks including two grade B leaks managed with antibiotics and one grade C leak requiring reoperation.

Median length of stay with AMNIOFIX recipients was 2 days (IQR 1.5-2 days).

One death (postop aspiration) unrelated to anastomotic integrity. No AMNIOFIX-related adverse events reported.

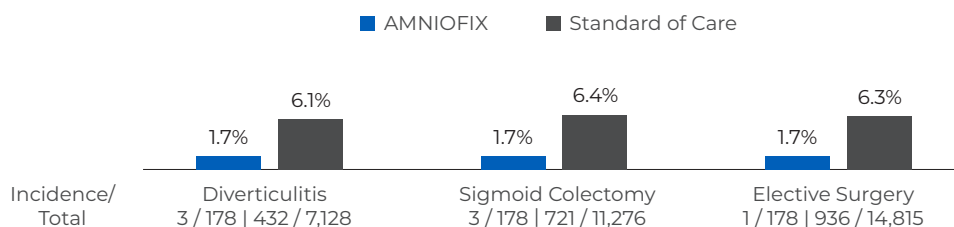
To provide contextual reference, the authors identified contemporary benchmarks from the peer-reviewed literature that most closely resembled the AMNIOFIX cohort in this study.

Postop Outcomes: AMNIOFIX¹ & Standard of Care Historical Benchmark (Beltzer, et al.)²



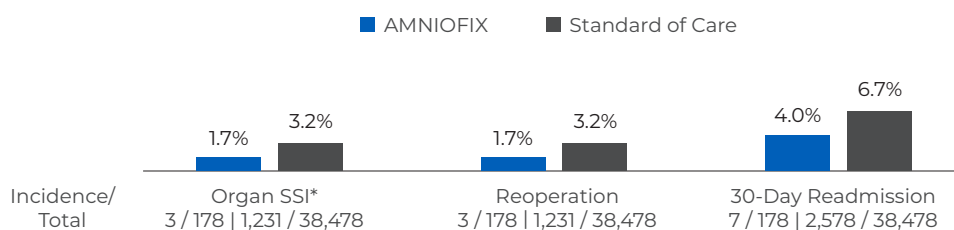
Results (cont.):

Anastomotic Leaks Postop: AMNIOFIX¹ & Standard of Care Historical Benchmark (PHD)³



PHD = Premier Healthcare Database.

Postop Outcomes: AMNIOFIX¹ & Standard of Care Historical (ACS-NSQIP)⁴



ACS-NSQIP = American College of Surgeons – National Surgical Quality Improvement Program.

*OSI = Organ/space surgical site infection. This was used as a surrogate for anastomotic leak, which may have underestimated true leak incidence, providing for a conservative benchmark.

Discussion:

- Anastomotic leaks are the most serious complication of colorectal surgery, leading to increased morbidity, mortality, Length of Stay (LOS), rehospitalizations, and healthcare costs.^{5,6}
- Lee et al. reported an anastomotic leak rate of 5% with a corresponding readmission rate of 13.9%.⁶
- Leaks were associated with an additional 7 days of LOS and an 88% increase in hospitalization costs among commercially insured patients, with greater increases (12 days LOS, 167% higher costs) among Medicare patients.⁶
- Adjusted for 2025 inflation, these costs approximate \$42,000 and \$30,000 for Medicare and commercial patients, respectively.⁷
- Readmissions contribute significantly to healthcare costs following colorectal surgery; in the present cohort, a low all-cause readmission rate was observed.
- These findings should be interpreted in light of the study's retrospective design, absence of a contemporaneous control group, and potential confounding factors inherent to observational analyses. While these results are encouraging, they do not establish a causal relationship or comparative effectiveness.

To find out more about MIMEDX products:

Call **866.477.4219** Email: customerservice@mimedx.com

1. Das B, et al. Eur Surg Res. Published online March 20, 2026. 2. Beltzer C, et al. Adv Surg Tech A. 2019;29(11):1451-1455. 3. Wang T, et al. J. Int J Colorectal Dis. 2023;38:264. 4. Ore AS, et al. Trends in the management of nonemergent surgery for diverticular disease and the impact of practice parameters. Am Surg. 2023;89(11):4590-4597. 5. Hammond J, et al. J Gastrointest Surg. 2014;18(6):1176-1185. 6. Lee SW, et al. Surg Endosc. 2020;34:4374-4381. 7. U.S. Bureau of Labor Statistics. CPI inflation calculator. https://www.bls.gov/data/inflation_calculator.htm. Accessed June 19, 2025.

This study was financially supported by an unrestricted research grant from the MIMEDX Group, Inc. MIMEDX was not involved in the data collection, analysis, or write up of the study. The authors of this study are paid consultants of MIMEDX Group, Inc. This information is provided for educational purposes only and is not meant to direct clinical decision making. See Instructions for Use for complete information including tissue use.

AMNIOFIX and MIMEDX are trademarks of MIMEDX Group, Inc. ©2026 MIMEDX Group, Inc. All Rights Reserved. mimedx.com US-AM-2600051 v1.0

