



CASCADe 2027 NON-CONFIDENTIAL SUMMARY »

Simpl-E-Vac: Ready-to-Use Endoscopic Vacuum Therapy for Gastrointestinal Leaks

Overview

Gastrointestinal (GI) leaks, perforations or breakdowns at surgical connection sites in the digestive tract, are a life-threatening complication of GI surgery and disease, and no FDA-cleared device currently exists in the United States to treat them. Clinicians must hand-build makeshift devices in the operating room using external wound-vacuum sponges, sutures, and feeding tubes, a process that can take up to 90 minutes and varies by clinician and institution. Simpl-E-Vac is a ready-to-use endoscopic vacuum therapy (EVT) kit that pairs a nasogastric tube with a pre-sized, self-expanding sponge encased in a dissolvable casing, reducing device preparation and deployment to under two steps.

- Eliminates the improvised, hand-assembled nature of current EVT devices, reducing preparation time and variability between clinicians and institutions.
- Uses a segmented, dissolvable casing to keep the sponge compressed for easy insertion, allowing it to expand and conform to the leak site once positioned.
- Has advanced through bench testing and initial human feasibility use at UW Medicine, with a next-generation platform already in development.

Description

Modality: Medical device (endoscopic vacuum therapy system). **Indication:** Gastrointestinal leaks, perforations, and fistulas in adult patients, used in conjunction with standard endoscopic procedures.

The device consists of a modified nasogastric tube fitted with a compressed, porous fluid-collection element (sponge) held in place by a segmented, dissolvable casing. A guidewire assists in navigating the compressed sponge to the leak site, where endoscopic visualization confirms placement. Once positioned, the casing dissolves on contact with bodily fluids, allowing the sponge to expand and conform to the wound; the tube is then connected to an external vacuum source to apply continuous negative pressure, promoting drainage, blood flow, and tissue healing. The kit is designed to be available in multiple pre-set sizes.

- Bench and in vitro testing have validated sponge compression ratios, casing dissolution timing, and vacuum performance.
- The device has advanced to initial human feasibility use at UW Medical Center under an approved research protocol.

COMOTION REFERENCE »

BDP 8617

INNOVATION MANAGER »

Judy Bridges

SECTOR »

Medical Device

LEAD INVESTIGATOR »

Adam Templeton, MD, Division of Gastroenterology, UW Medicine, University of Washington

CO-INVENTOR »

Eric Seibel, PhD, Mechanical Engineering, University of Washington

UNIVERSITY OF WASHINGTON

COMOTION »

1100 NE Campus Parkway, # 200
Seattle, WA 98195

Tel: (206) 543-3970

uwcomotion@uw.edu

comotion.uw.edu

- A second-generation platform, integrating vacuum therapy with a customizable silicone stent designed to preserve oral feeding during treatment, is already in development, building on the core intraluminal vacuum technology.

Technology Readiness Level (TRL)

TRL 7 — Full system prototype tested in an actual operational environment. The device has completed bench and in vitro validation, been manufactured and sterilized for clinical use, and been evaluated in initial human feasibility cases at UW Medical Center under an approved research protocol, with further clinical validation and next-generation prototyping currently underway.

Value Proposition

- Reduces device preparation and deployment from up to 90 minutes to a fraction of that time, minimizing time under anesthesia for a life-threatening condition.
- Standardizes a currently improvised, off-label procedure into a purpose-built, pre-assembled kit that does not vary by clinician or institution.
- Uses low-cost, readily available hospital materials, supporting a manufacturing cost structure compatible with broad hospital adoption.
- Is compatible with existing nasogastric tube and external wound-vacuum infrastructure already present in most hospitals, minimizing new equipment needs.
- Addresses a clinical space with no FDA-cleared device currently available in the United States, positioning the technology for first-mover advantage.

Intellectual Property Position

[US20250352715A1](#) - Patent application pending.

This filing covers the core transnasal endoscopic vacuum therapy platform, including the compressible sponge, segmented dissolvable casing, and tube attachment systems. A second-generation platform, a customizable, feeding-compatible silicone stent that integrates with the vacuum therapy system, is already in development and is expected to be protected through additional intellectual property filings as it matures.

Market Opportunity

- Target customers include gastroenterologists and GI surgeons at hospitals that treat GI leaks, perforations, and anastomotic complications, particularly high-volume academic and tertiary referral centers.
- Hospital value analysis committees and procurement teams are key institutional buyers, as most hospital systems evaluate new endoscopic devices through these committees before adoption.
- A significant unmet need exists because there is currently no FDA-cleared device for endoscopic vacuum therapy in the United States, forcing clinicians to build improvised devices for each case.
- Customer discovery interviews with gastroenterologists and GI surgeons indicate strong interest in a standardized, ready-to-use device that reduces procedure time and clinical variability.

- The global vacuum therapy device market was valued at approximately \$1.9 billion in 2022, with the internal/luminal surgical vacuum therapy segment representing a smaller, more targeted opportunity within that market.

References

1. Ribeiro et al., "The Clinical and Economic Burden of Colorectal Anastomotic Leaks: Middle-Income Country Perspective," *Gastroenterology Research and Practice*, 2019.
2. Livingstone, Imogen, et al., "Current Status of Endoscopic Vacuum Therapy in the Management of Esophageal Perforations and Post-Operative Leaks," *Clinical Endoscopy*, vol. 54, no. 6, 2021, pp. 787-97. <https://doi.org/10.5946/ce.2021.240>
3. Hwang JJ, Jeong YS, Park YS, Yoon H, Shin CM, Kim N, Lee DH, "Comparison of endoscopic vacuum therapy and endoscopic stent implantation with self-expandable metal stent in treating postsurgical gastroesophageal leakage," *Medicine (Baltimore)*, 95:e3416, 2016.
4. Eichelmann, Ann-Kathrin, et al., "Economic Burden of Endoscopic Vacuum Therapy Compared to Alternative Therapy Methods in Patients with Anastomotic Leakage After Esophagectomy," *Journal of Gastrointestinal Surgery*, vol. 25, no. 10, 2021, pp. 2447-54. <https://doi.org/10.1007/s11605-021-04955-w>