Democratizing Placement of Endoluminal Negative Pressure Devices for Gastrointestinal Leaks

Preliminary Product Design Specifications

BME 301 Lab 301

Team Members:
Simon Fetherston (Leader)
Mariah Smeeding (Communicator)
Evelyn Mikkelson (BSAC)
Yeanne Hwang (BPAG, BWIG)

Client: Dr. Amber Shada
Advisor: Prof. John Puccinelli

February 5, 2026

Function:

메모 포함[1]: Evelyn Mikkelson

Traditionally, large defects in the gastrointestinal (GI) tract are treated with surgery. Recently, some surgeons have had success utilizing negative pressure therapy, which is used to improve healing of superficial wounds. The placement of the device in the GI tract is currently very labor intensive and requires skillful manipulation of an endoscope. Development of a streamlined procedure to deploy negative vacuum therapy in the GI tract would make the therapy accessible to more surgeons.

Client requirements:

메모 포함[2]: Simon Fetherston

- The client requires an endoscopic vacuum therapy device capable of delivering a sponge to a cavity within the gastrointestinal tract.
- The client requires the device to be used to treat gastrointestinal leaks with a minimum cavity size of 2cm.
- The client requires the device to be deployable in conjunction with the use of current clinical endoscopes.
- The client prefers the design to be compatible with V.A.C Grandufoam Dressings, enabling integration with existing clinical materials.
- The client intends the device to be suitable for use in both the upper and lower gastrointestinal tracts.
- The client intends the device to have single patient use to reduce the risk of cross-contamination and infection.
- The client requires the device to be suitable for use with patients under anesthesia b.

Design requirements:

1. **Physical and Operational Characteristics**
   a. *Performance requirements*

메모 포함[3]: Evelyn Mikkelson

      i. The device must retain the same properties as current EndoVAC therapy. This includes macro and microdeformation of tissue, increased perfusion, fluid removal, and bacterial clearance [1].
      ii. Allow intracavity or intraluminal placement of the sponge [1].

b. *Safety*

i. The combined diameter of components utilized simultaneously must be smaller than 2-3cm in diameter to prevent trauma to the upper esophageal sphincter [1].

ii. The design must consider proper fixation of the nasogastric tube to prevent continuous compression of the nasal wall, which leads to nasal wing necrosis and nose deformation [2].

iii. Formation and rupture of a pseudoaneurysm within the aorta and its branches is a risk during vacuum therapy in the upper gastrointestinal tract [2].

iv. Increased time of contact between the tissue and absorbent material increases ingrowth that can cause minor bleeding when removed [3].

c. *Accuracy and Reliability*

i. The device must retain or improve upon the current success rate of 90%.

d. *Life in Service*

i. The device must be replaced every 3-7 days [3].

ii. The device has to stand up to pressures used in current EndoVAC therapy, 125mmHg - 175mmHg [1].

e. *Shelf Life*

i. The device shall be able to remain within sterile packaging for up to 3 years without losing functionality

f. *Operating Environment*

i. Internal components (in situ with GI tract)

1. Temperature will be approximately body temperature (36-38°C) for the duration of therapy.
2. 100% relative humidity should be assumed as the device will be fully saturated with bodily fluids including gastric secretions, bile, pancreatic enzymes, intestinal contents, and blood.
3. Chemical exposure will differ depending on the region of the GI tract.
    a. Upper GI: gastric acid (pH 1.5-3.5).
    b. Lower GI: intestinal contents (pH 5.5-8), includes digestive enzymes, pepsin, bile salts, pancreatic enzymes, fecal matter.
4. There will be continuous negative pressure applied to the sponge per clinical protocol.

메모 포함[4]: Evelyn Mikkelson

메모 포함[5]: Evelyn Mikkelson

메모 포함[6]: Evelyn Mikkelson

메모 포함[7]: Simon Fetherston

메모 포함[8]: Mariah Smeeding

5. Mechanical force such peristaltic movements and patient motion should be considered
6. Within a biological environment: in contact with mucosal tissue, exposure to endogenous bacteria and potential pathogens.

g. *Ergonomics*

메모 포함[9]: Simon Fetherston

i. Implantation of the device shall be less than 2 hours to reduce strain on the surgeon and reduce the risk of procedure-related complications.
ii. During implantation, the product must remain stable to ensure safe and effective placement within the gastrointestinal tract.
iii. The device shall be capable of being installed by a single surgeon without the application of excessive force.
iv. The device should be able to be implanted by a first time user without extensive prior training as to reduce the likelihood of user error
    1. An external instruction manual shall be used as the product is a Class II medical device [4].

h. *Size*

메모 포함[10]: Mariah Smeeding

i. The outer diameter of both the vacuum/drainage catheter and foam sponge together must be small enough to pass atraumatically through the esophagus or colon alongside or through an endoscope (typically around 2cm), while maintaining sufficient size for effective drainage and structural integrity.
ii. The foam sponge alone:
    1. Should accommodate GI leaks with defect sizes of 2-15 cm; defects larger than 15-18 cm may not be suitable for sponge-based therapy due to anatomical constraints of the GI tract.
    2. Must compress to a low profile for ease of deployment through GI tract.
    3. Must be able to expand sufficiently upon deployment into the cavity to conform to and fill the irregular space.

i. *Weight*

메모 포함[11]: Mariah Smeeding

i. Lightweight to prevent device migration due to gravity, peristalsis, or patient movement. Device must remain securely positioned within the cavity throughout the treatment period without causing pressure-related tissue injury.

j. *Materials*

메모 포함[12]: Mariah Smeeding

i. All materials must be biocompatible per ISO 10993 standards for devices in prolonged contact with mucosal tissue (>24 hours) [5X]
ii. Material must maintain structural integrity throughout treatment duration (typically 3-7 days) and be removable intact via endoscopy. [3]
iii. Materials must not elicit inflammatory or immune responses in the GI tract
iv. The material must have an open-pore structure to allow fluid permeability which enables effective drainage of fluids and secretions under negative pressure.
v. Material must be able to conform to irregular defect geometries and tolerate GI peristalsis without tissue trauma.
vi. Must withstand exposure to gastric acid (pH 1.5-3.5), bile, pancreatic enzymes, and other GI secretions without degradation.
vii. Current materials used for sponge include:
   1. Polyurethane (PU) open-pore sponges: most commonly used material in endoVAC applications due to its favorable drainage properties and flexibility. KCL black polyurethane foam, originally designed for external wound VAC therapy, is frequently adapted for endoluminal use. Other medical grade PU foams with varying pore sizes and densities are used in prototype and commercial devices such as the Eso-SPONGE. [6] [7]

k. *Aesthetics, Appearance, and Finish*

메모 포함[13]: Mariah Smeeding

i. Foam Portion Appearance:
   1. Conformability: foam must be soft and pliable to bend and conform to anatomical curves and irregular leak cavities without causing mucosal trauma.
   2. Texture: Open-pore reticulated structure with interconnected pores to enable effective cavity geometries.
   3. Shape: Cylindrical with tapered end to facilitate insertion and positioning within irregular cavity defects.
   4. Surface finish: smooth, non-abrasive outer surface to minimize friction and tissue injury during deployment through the esophagus or colon.
ii. Vacuum/drainage catheter

1. Flexibility and torqueability: Catheter must have sufficient column strength and torque transmission to allow controlled positioning and deployment into the defect cavity, while remaining flexible enough to navigate anatomical curves (esophagus, stomach, colon)
2. Surface finish: Smooth outer coating to facilitate easy passage through GI tract.
3. Length: Adequate length to reach target locations in upper GI (esophagus, stomach, duodenum) and lower GI (colon, rectum) tracts.

iii. Overall Design:

1. Compactness: Device should compress sufficiently for passage through the GI tract and then expand within the cavity to fill defect space.
2. Deployment and handling: Design should minimize technical difficulty during cavity deployment through smooth surfaces and compatibility to be manipulated with forceps for precise positioning. All edges, connections, and surfaces must be smooth and rounded to prevent tissue trauma.

2. Production Characteristics

a. Quantity

메모 포함[14]: Yeanne Hwang

i. The device is designed for single-patient use in endoluminal negative pressure therapy. Clinically, endoluminal vacuum therapy (EVT) requires foam exchange approximately every 7 days due to secretion accumulation, decreased suction efficiency, and tissue ingrowth. Reported clinical data indicate an average EVT duration of 35.8 days, with a mean of 7.2 foam exchanges per patient [2]. Based on these findings, this project aims to develop a system capable of supporting up to 30 foam exchanges per patient, while utilizing a single functional deployment device.

b. Target Product Cost

메모 포함[15]: Yeanne Hwang

i. The initial budget for the project is $500 to $1,000, and this will be the target cost per unit.

ii. The client will provide current equipment used to construct VACs (foam, nasogastric tube, suture) and endoscopy if needed.

3. Miscellaneous

a. *Standards and Specifications*

메모 포함[16]: Simon Fetherston

i. Endoscopes and accessories are classified as Class II medical devices since the equipment can pose moderate risk to patients during operation [4].

  1. EnoVAC devices, including sponges, are Class II (special control) devices subject to premarket notification 501(k). If the proposed device is not substantially equivalent to a predicate device, clinical trials are required for premarket approval [8].

ii. The International Organization for Standardization (ISO) has multiple standards that apply to the development of endoscopic devices for use within the gastrointestinal tract.

  1. ISO 10993 defines requirements for biomaterials if they come in contact with the body [5].
    a. ISO 10993-1 section 6.4.4.4 requires biological effects to be evaluated for medical devices in contact with intact mucosal membrane [5].
    b. ISO 10993-1 section 6.4.4.4 requires biological effects to be evaluated for medical devices in contact with breached or compromised surfaces or internal tissue other than circulating blood [5].
  2. ISO 8600 defines the requirements for endoscopes and endotherapy devices used in the practice of medicine [9].
    a. ISO 8600-4 requires that the maximum width of the insertion portion must be determined to ensure compatibility with human anatomy and other devices [9].
  3. ISO 14971 requires the application of risk management to estimate the probability of occurrence of harm and the consequences of such harm [9].

b. *Customer*

메모 포함[17]: Yeanne Hwang

i. The primary customer is the endoscopic and laparoscopic gastrointestinal surgeon at UW Hospital, represented by the client, Amber L. Shada. The device must support a simplified EVT deployment system that reduces procedural complexity and enables wider clinical use.

ii. Patients receiving EVT include individuals with upper or lower gastrointestinal transmural defects, most commonly postoperative anastomotic leaks following esophageal, gastric, or colorectal surgery, with this project focusing primarily on upper GI tract patients [1].

iii. This population also includes patients with infected cavities or abscesses who are already receiving antibiotic therapy.

c. *Patient-related concerns*

메모 포함[18]: Evelyn Mikkelson

i. Nasogastric tubes cause patient discomfort, especially for those also using a nasoenteric tube [1].

ii. Multiple procedures to exchange the sponge causes patient distress [1].

iii. Although there is not a well known cause, treatment of anastomotic leaks can lead to esophageal and stomach strictures. Strictures require an additional procedure, dilation, to treat [2].

d. *Competition*

메모 포함[19]: Simon Fetherston

i. The Endo-SPONGE® and Eso-SPONGE®, developed by B. Braun Melsungen, are minimally invasive methods for treatment of anastomotic leakage [10]. The Endo-SPONGE® is used in the low pelvic area while the Eso-SPONGE® is used in the upper gastrointestinal tract. The method utilizes an endoscope, an overtube, and a polyurethane sponge. The overtube and endoscope are used to place the sponge in the gastrointestinal defect. Controlled continuous negative pressure of 100-125 mmHg is applied via a transnasal gastric tube using an electronic vacuum pump. The system comes prepackaged and is available for purchase from Boston Scientific.

ii. The Suprasorb® CNP is an open-pore film drainage system that has been adapted for treatments of anastomotic leaks [11]. The system includes a perforated film that is attached to a 16F gastric decompression tube using a suture. This film drainage system is then passed to the desired treatment location using the guidance of an 8F feeding tube. Once the film is in place, negative pressure is applied to treat small defects. This treatment option offers reduced adhesiveness of the film compared to a sponge, easy removal, and decreased damage to surrounding tissue.

Works Cited

메모 포함[20]: Simon Fetherston

[1] D. T. H. de Moura et al., “Role of endoscopic vacuum therapy in the management of gastrointestinal transmural defects,” World J Gastrointest Endosc, vol. 11, no. 5, pp. 329–344, May 2019, doi: 10.4253/wjge.v11.i5.329.

[2] D. T. H. de Moura, B. S. Hirsch, P. H. B. V. Ribas, S. Q. Silveira, H. G. Guedes, and A. M. Bestetti, “Endoscopic vacuum therapy: pitfalls, tips and tricks, insights, and perspectives,” Transl Gastroenterol Hepatol, vol. 9, p. 50, Jul. 2024, doi: 10.21037/tgh-23-86.

[3] N. R. Smallwood, J. W. Fleshman, S. G. Leeds, and J. S. Burdick, “The use of endoluminal vacuum (E-Vac) therapy in the management of upper gastrointestinal leaks and perforations,” Surg Endosc, vol. 30, no. 6, pp. 2473–2480, Jun. 2016, doi: 10.1007/s00464-015-4501-6.

[4] “21 CFR 876.1500 -- Endoscope and accessories.” Accessed: Feb. 03, 2026. [Online]. Available: https://www.ecfr.gov/current/title-21/part-876/section-876.1500

[5] “ISO 10993-1:2025,” ISO. Accessed: Feb. 03, 2026. [Online]. Available: https://www.iso.org/standard/10993-1

[6] K. T. Jansen et al., “Differences in fluid removal of different open-pore elements for endoscopic negative pressure therapy in the upper gastrointestinal tract,” Sci Rep, vol. 12, p. 13889, Aug. 2022, doi: 10.1038/s41598-022-17700-3.

[7] Boston Scientific, "Eso-SPONGE Endoluminal Vacuum Therapy," Marlborough, MA, USA. [Online]. Available: https://www.bostonscientific.com/en-EU/products/endoluminal-vacuum-therapy/eso-sponge.html. Accessed: Jan. 29, 2026.

[8] “Product Classification.” Accessed: Feb. 03, 2026. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=FGS

[9] “ISO 8600-1:2025,” ISO. Accessed: Feb. 03, 2026. [Online]. Available: https://www.iso.org/standard/84216.html

[10] F. Richter et al., “Eso-Sponge® for anastomotic leakage after oesophageal resection or perforation: outcomes from a national, prospective multicentre registry,” BJS Open, vol. 6, no. 2, p. zrac030, Apr. 2022, doi: 10.1093/bjsopen/zrac030.

[11] R. Archid, F. Bazerbachi, M. C. Thomas, A. Königsrainer, and D. Wichmann, “Endoscopic negative pressure therapy for upper gastrointestinal leaks: description of a fashioned device allowing simultaneous enteral feeding,” VideoGIE, vol. 6, no. 2, pp. 58–61, Dec. 2020, doi: 10.1016/j.vgie.2020.10.009.