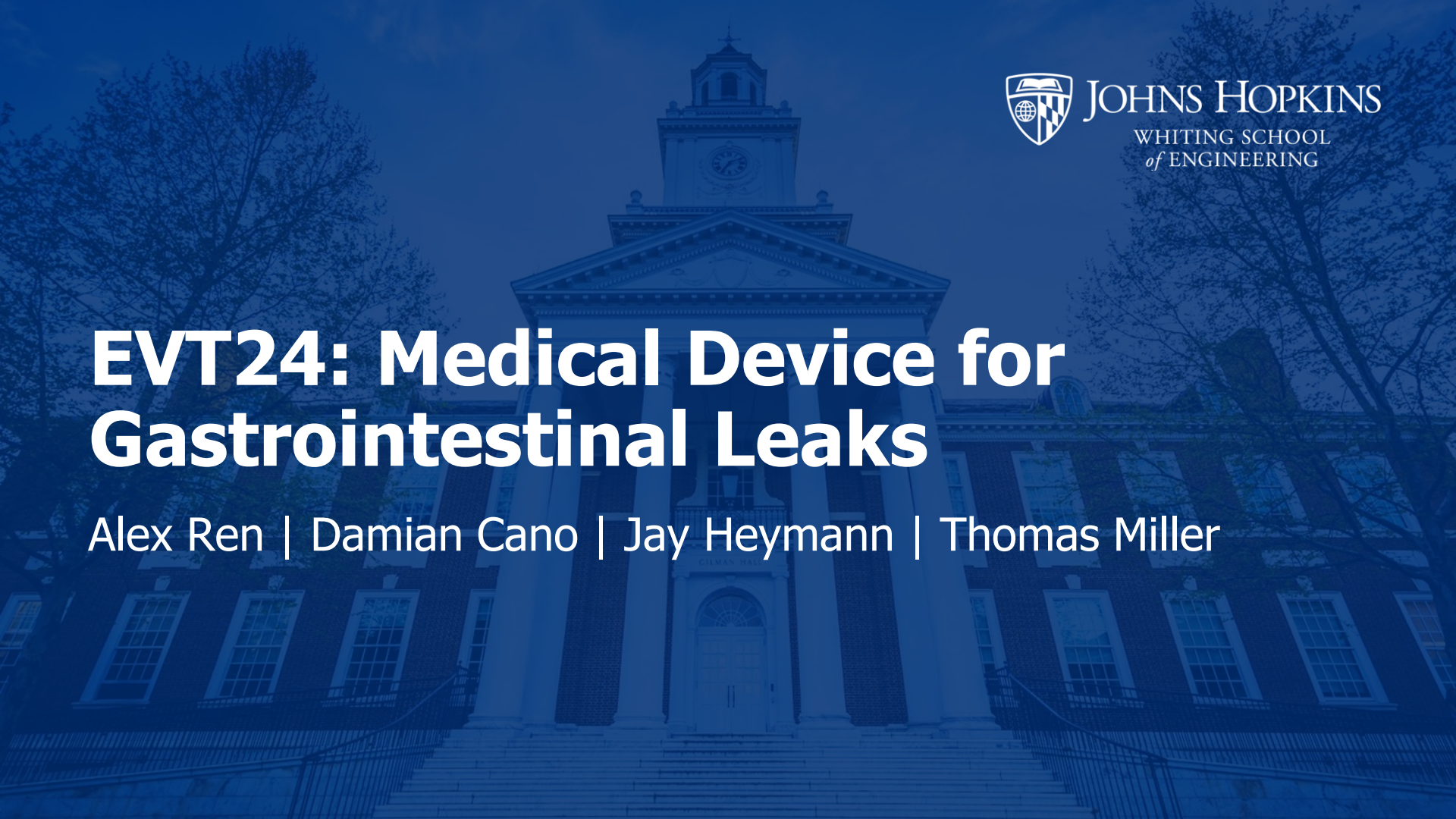
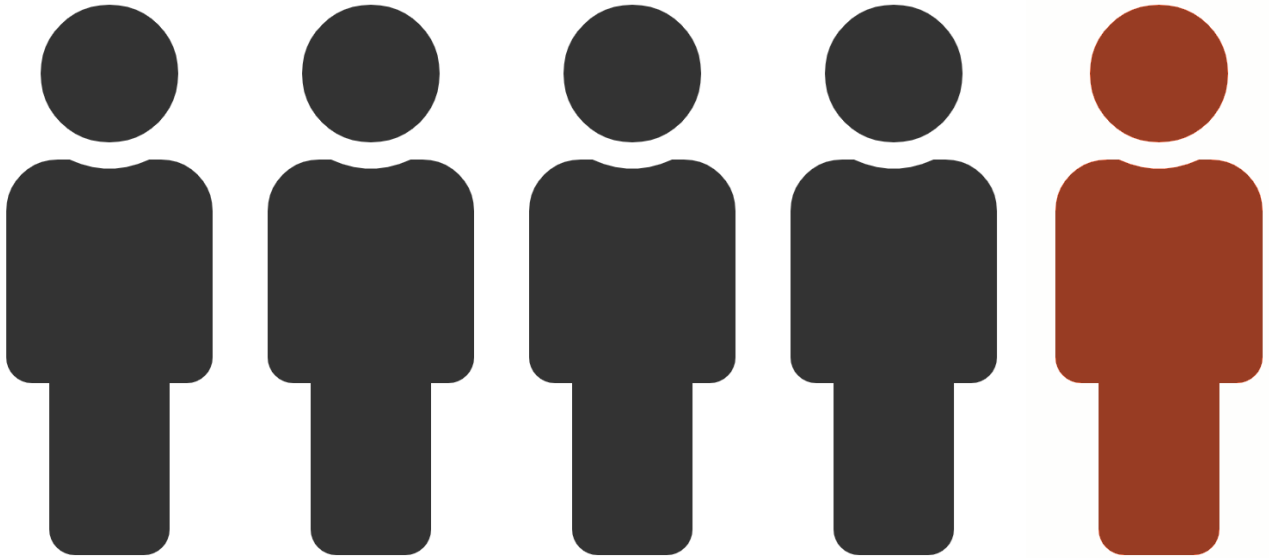


EVT24: Medical Device for Gastrointestinal Leaks

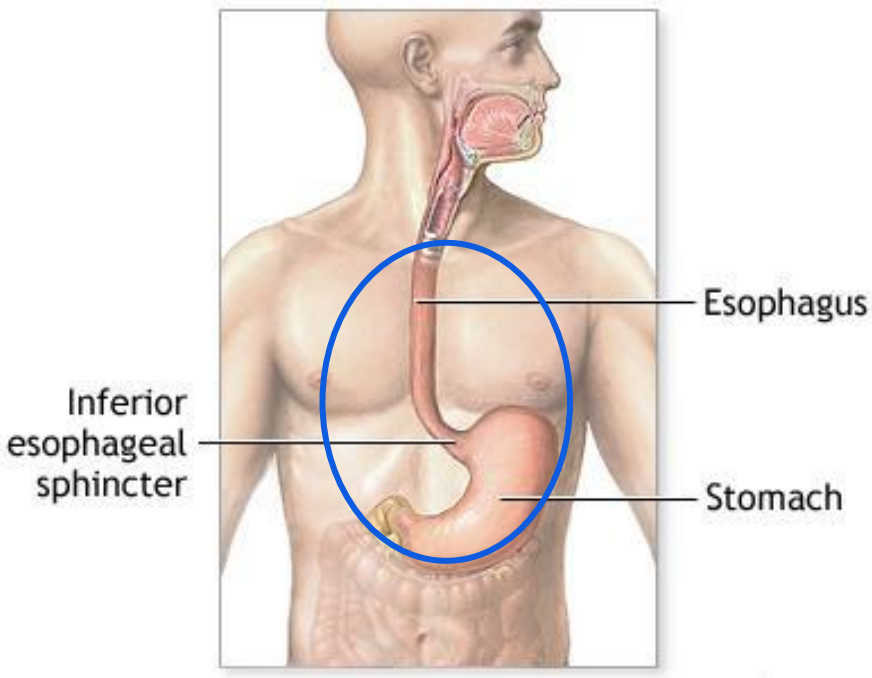
Alex Ren | Damian Cano | Jay Heymann | Thomas Miller

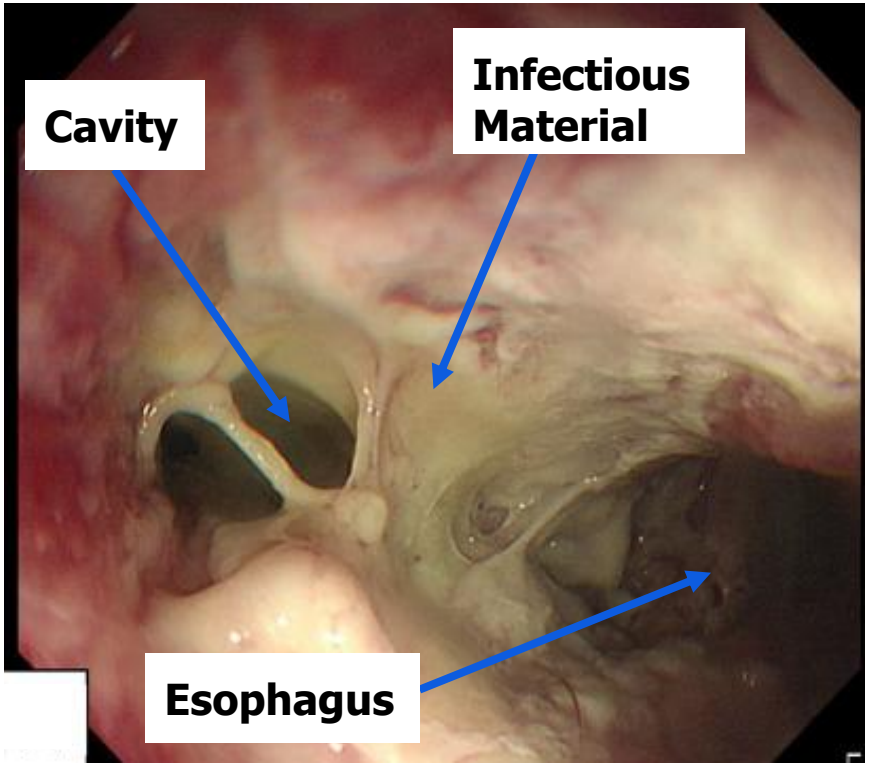
Problem Scenario

About 1 in 5 gastrointestinal leaks lead to death

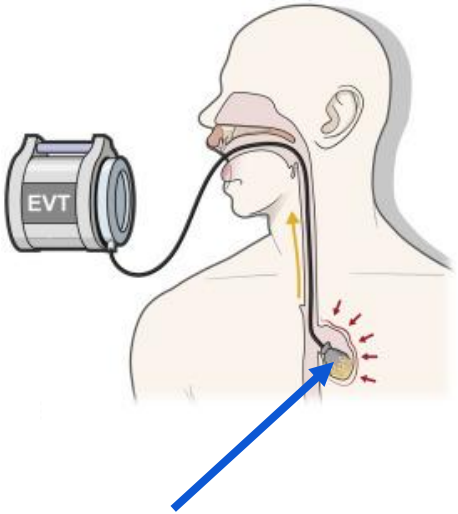


Problem Description

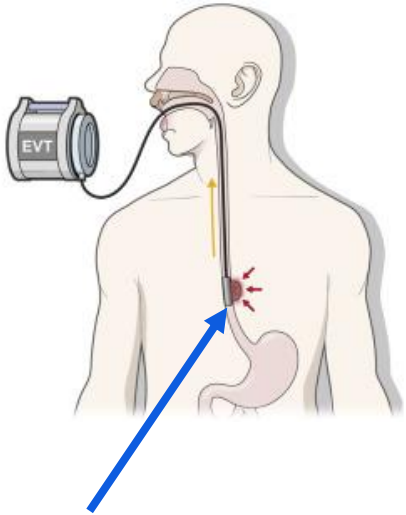




Endoscopic Vacuum Therapy

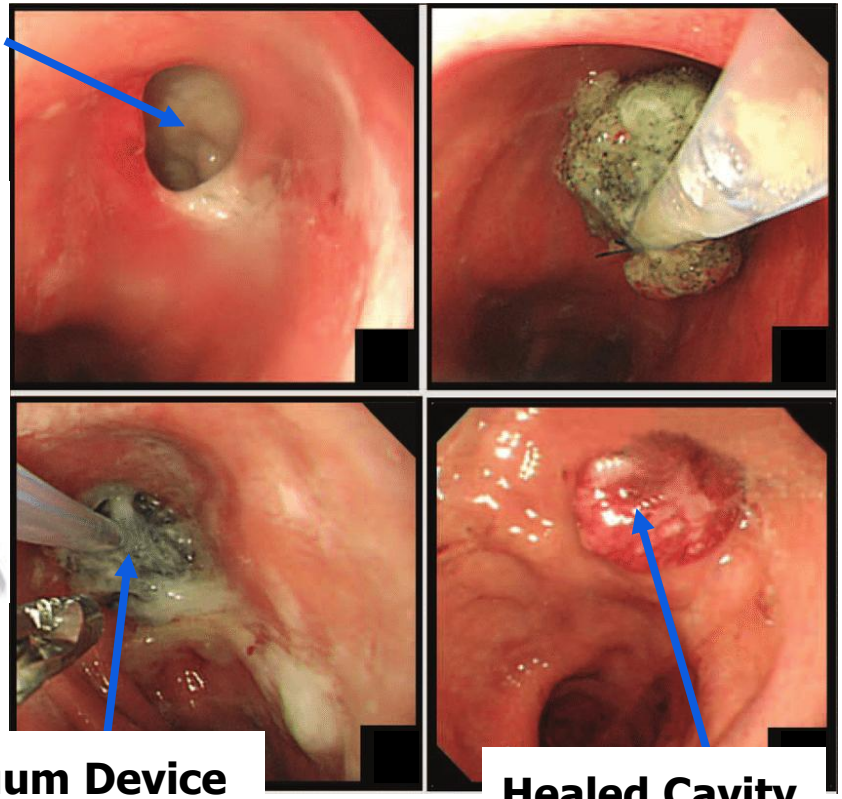


Extra-luminal



Intra-luminal

Cavity

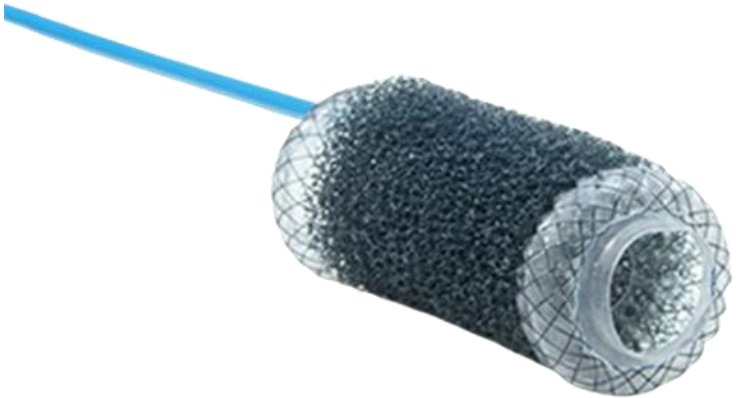


Vacuum Device

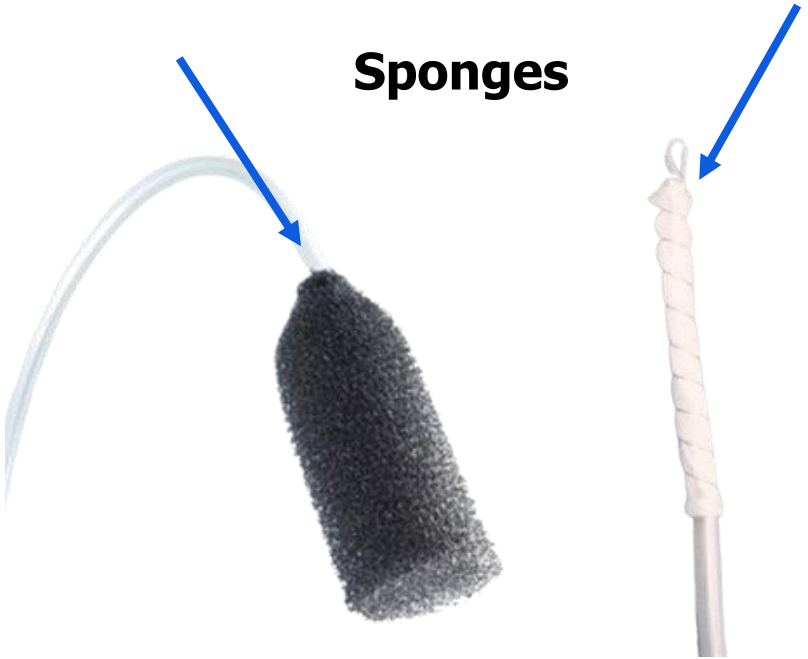
Healed Cavity

Current State

Vacuum Stents

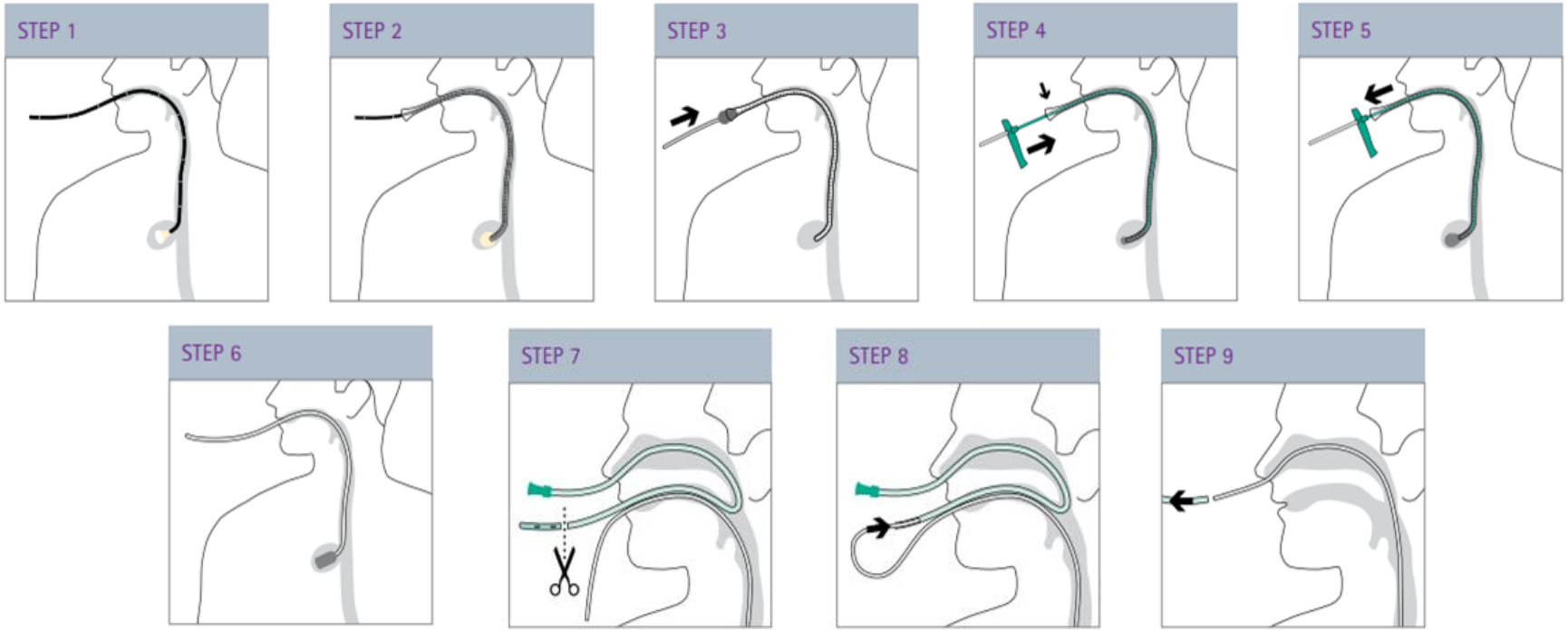


Sponges



Takeaway: There is no FDA approved EVT device, leaving physicians to construct “makeshift” devices.

EVT Procedure



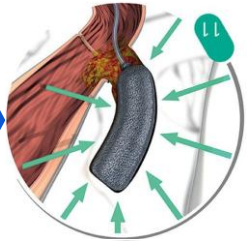
Design Requirements

- Procedure Time under an Hour

- Endoscopic Deployment

- Remain in Body for a Week

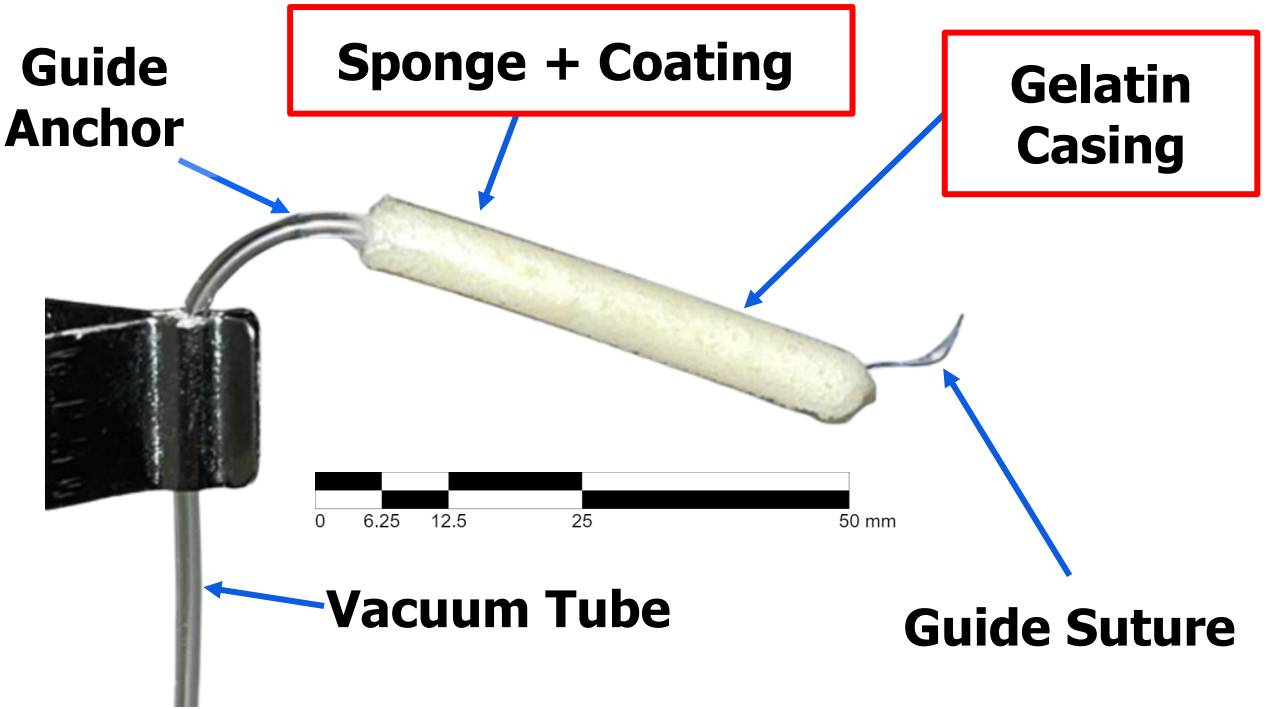
- Active Vacuum



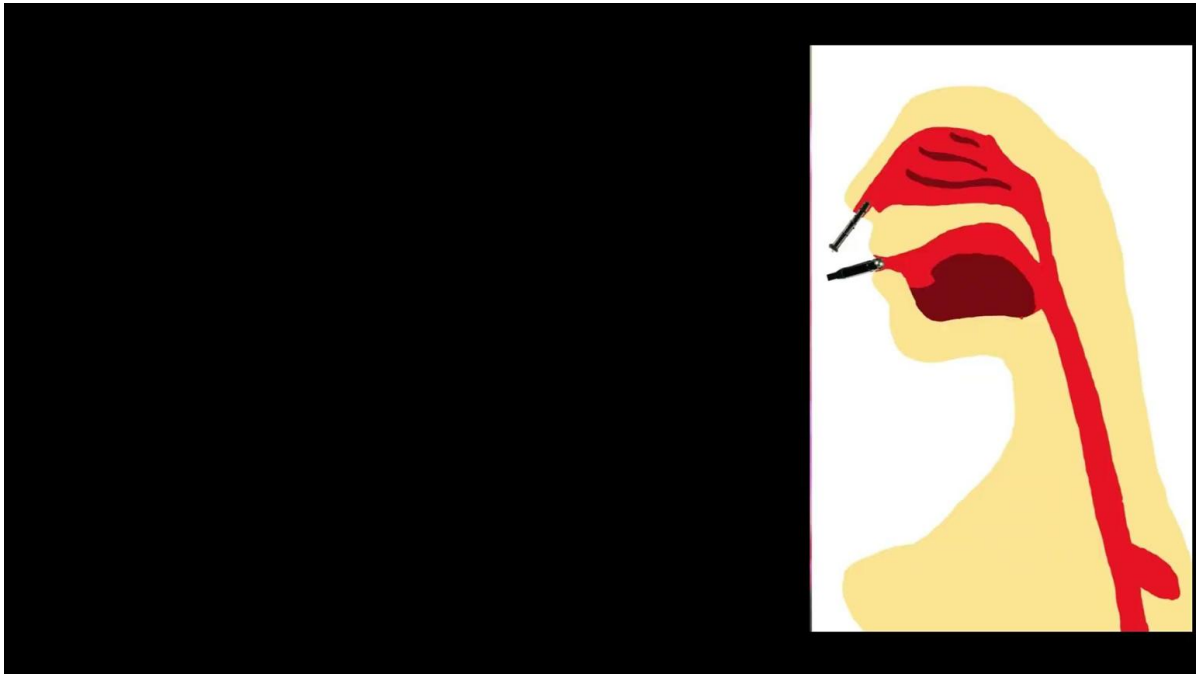
- Mass Production

- FDA Approval

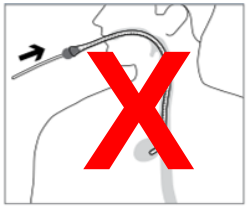
Device and Subsystems



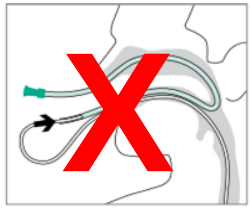
Video + Animation



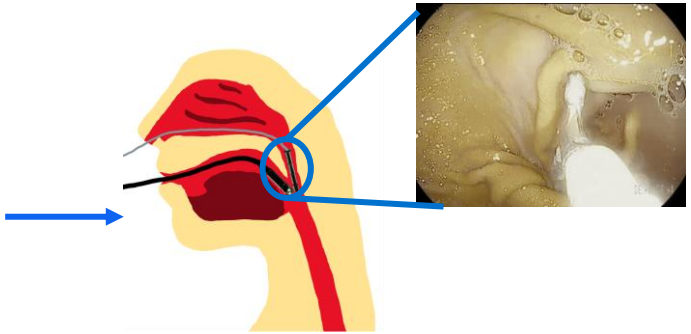
Improvements Over Endo/Eso Sponge



Use of Overtube

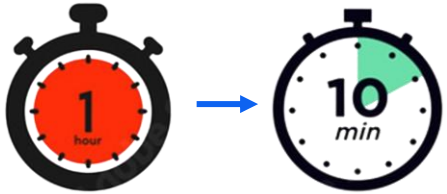


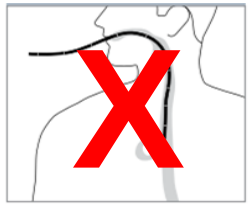
Passage From Mouth to Nose



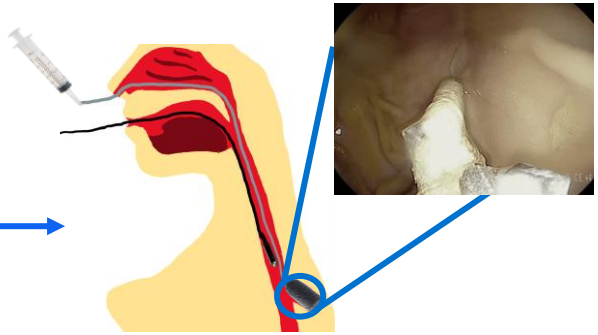
Streamlined Deployment

✓ Decreased Procedure Time





Post Endoscopic Evaluation



Simultaneous Endoscopic Evaluation

✓ Reduced Required Equipment

✓ Increased Patient Comfort

Gelatin Casing

0.5 mm wall thickness

⌀ 6mm

50mm

Simulated Pill Capsule Formula

Porcine Gelatin

Water Soluble

Gel Casing Manufacturing

Mix / Heat Gelatin Solution

Lower Mold Into Solution

Allow Casing to Cure

Remove Casing From Mold

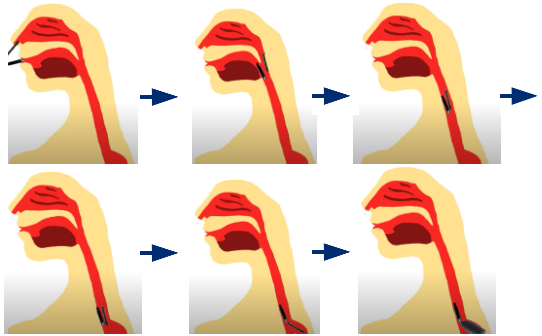
Alternative Molds With Cone

Gelatin Casing Testing

Partial Dissolution

Complete Dissolution

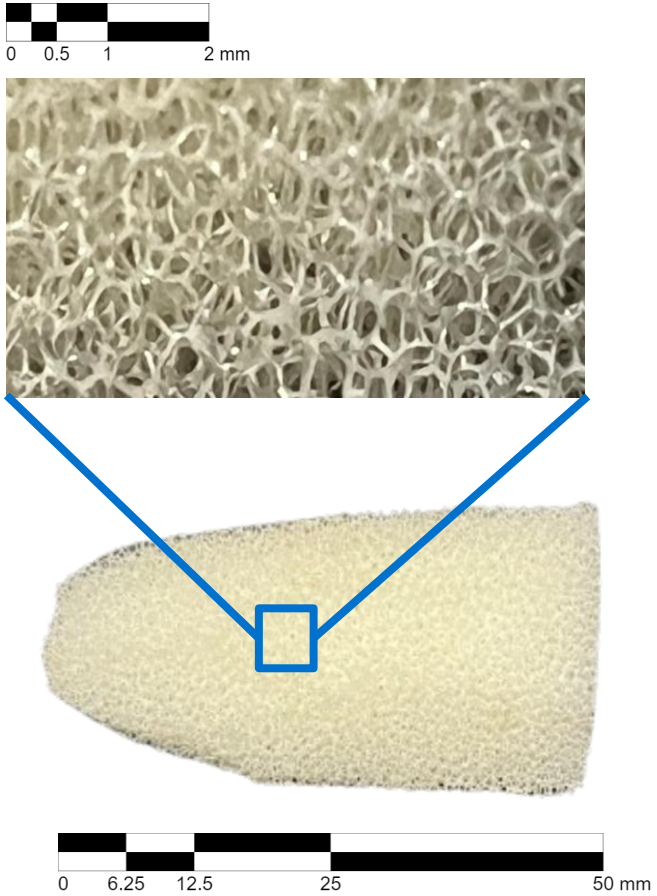
Procedure Steps



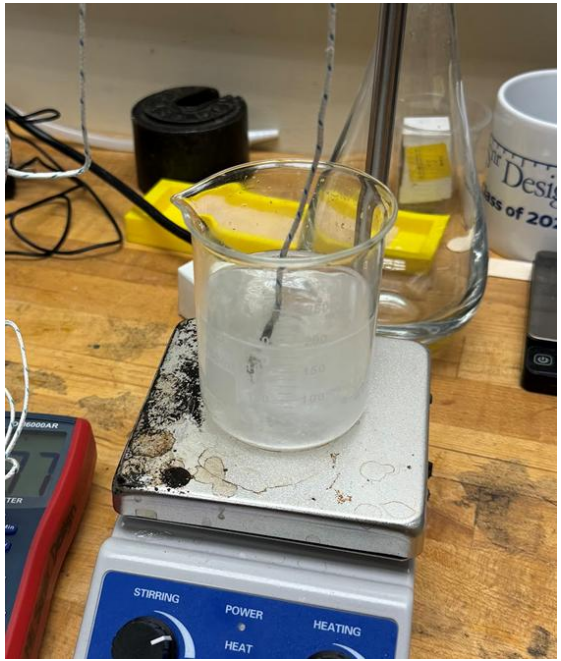
Average Partial Dissolution Time [min:sec]	Average Complete Dissolution Time [min:sec]	Estimated Procedure Time
6:50	8:53	10:00

Sponge Design

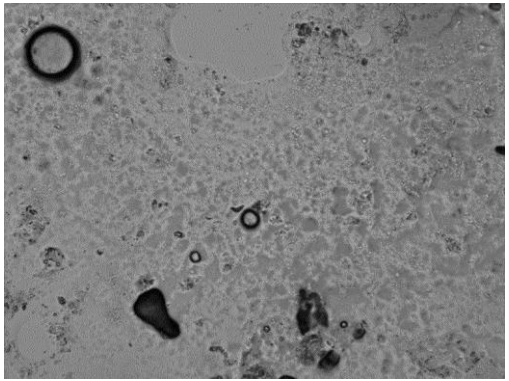
- Open-cell, cylindrical, 45 pores per inch, polyurethane sponge
- Biggest risk is tissue ingrowth, which is mitigated with two different coatings
  - Polyethylene glycol (**PEG**)
  - Poly lactic co-glycolic acid (**PLGA**)



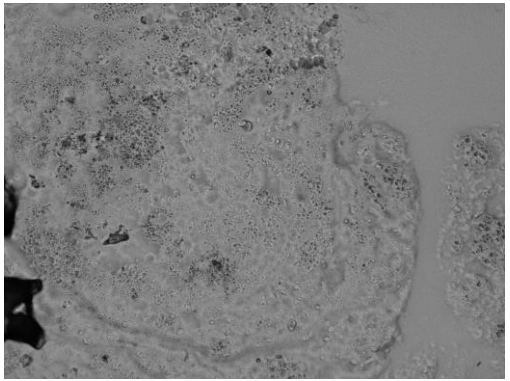
PEG-Coated Sponge



PEG Solution



No PEG

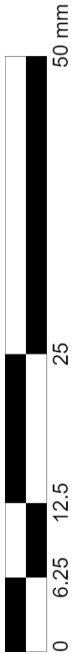


15% PEG

Images taken using scanning electron microscopy at 10x zoom.

Results: Inconclusive as there is no significant bacterial growth in either case.

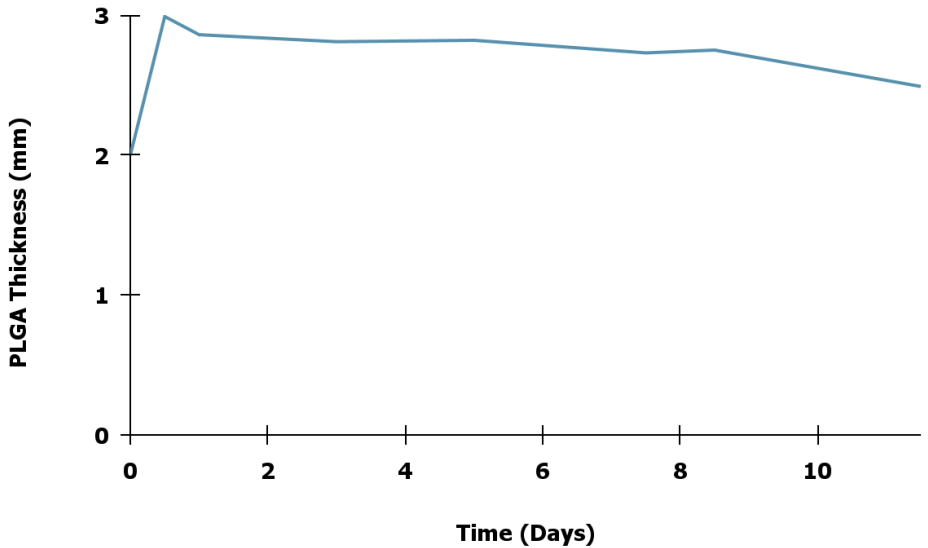
Bioabsorbable Layer



Polyurethane Sponge Covered in Bioabsorbable Layer

Bioabsorbable Layer (PLGA Scaffold)

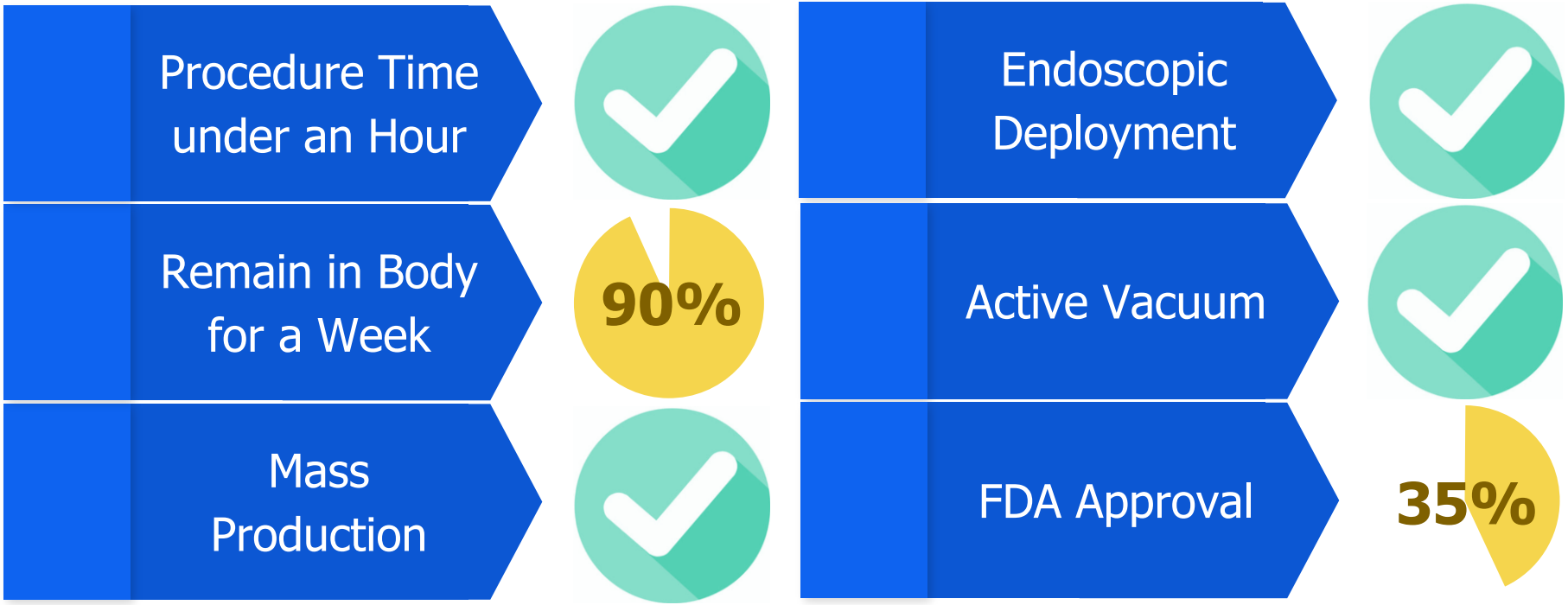
Dissolvability Testing



Results: Achieves 7 day minimum but rate of dissolution is slow.

Steps Forward

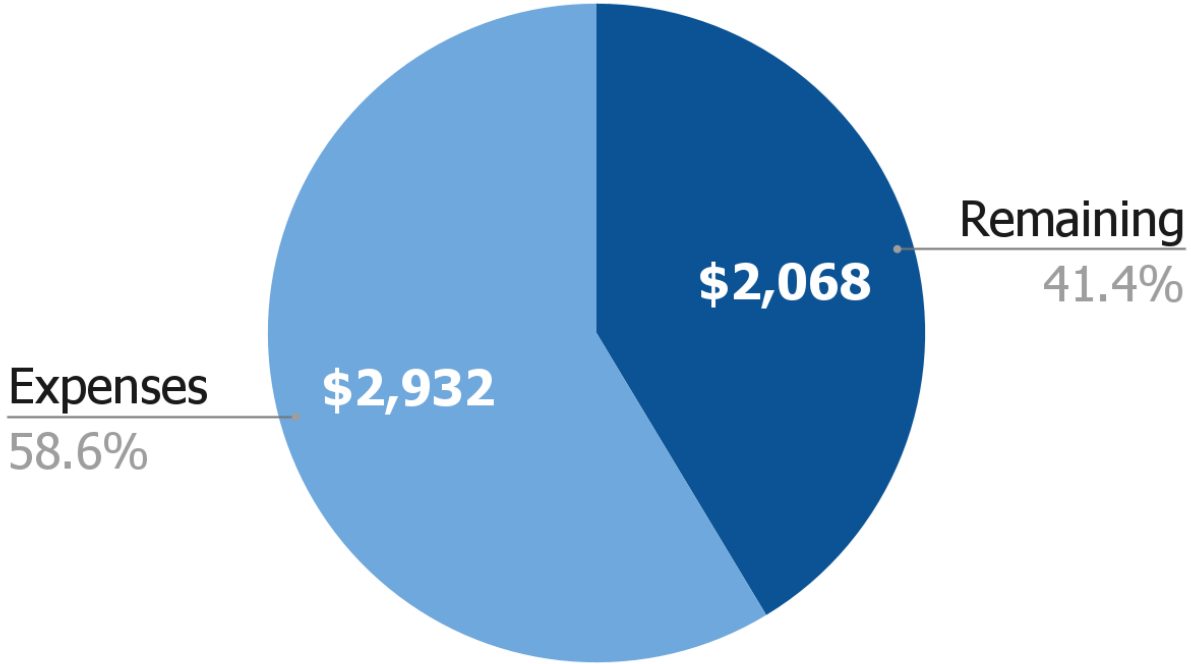
Requirements Closeout



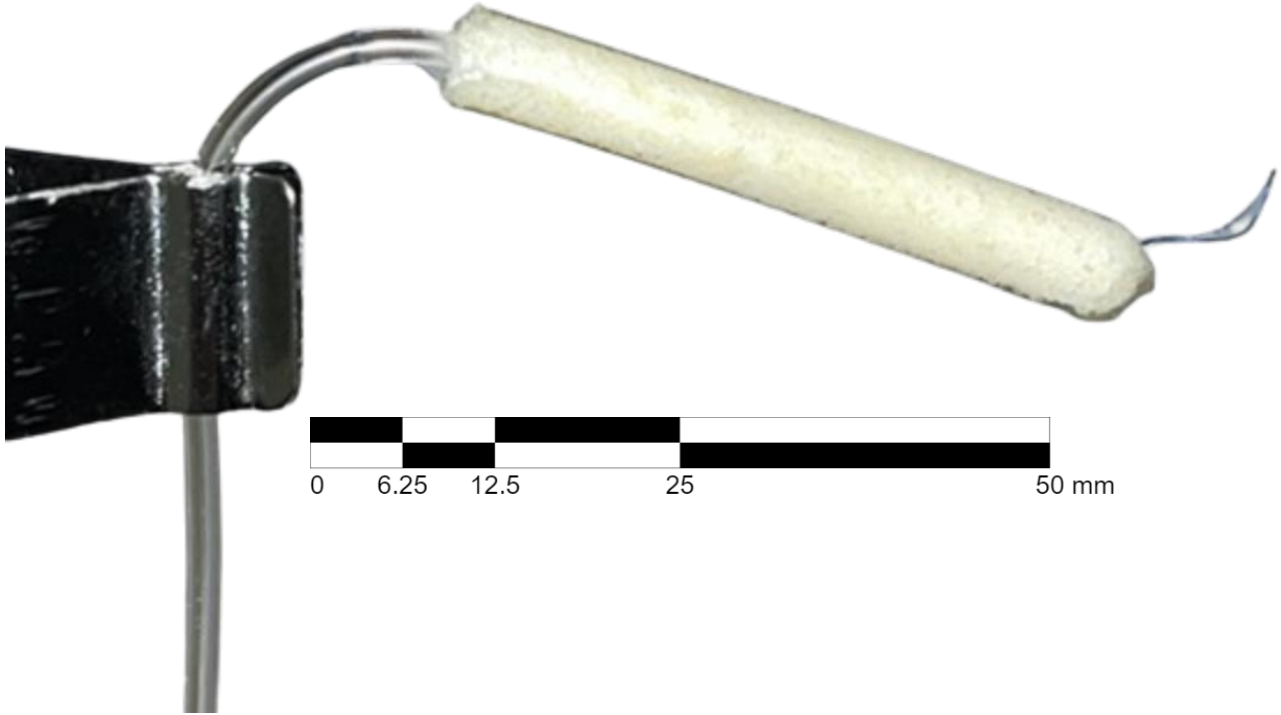
Budget and Unit Cost

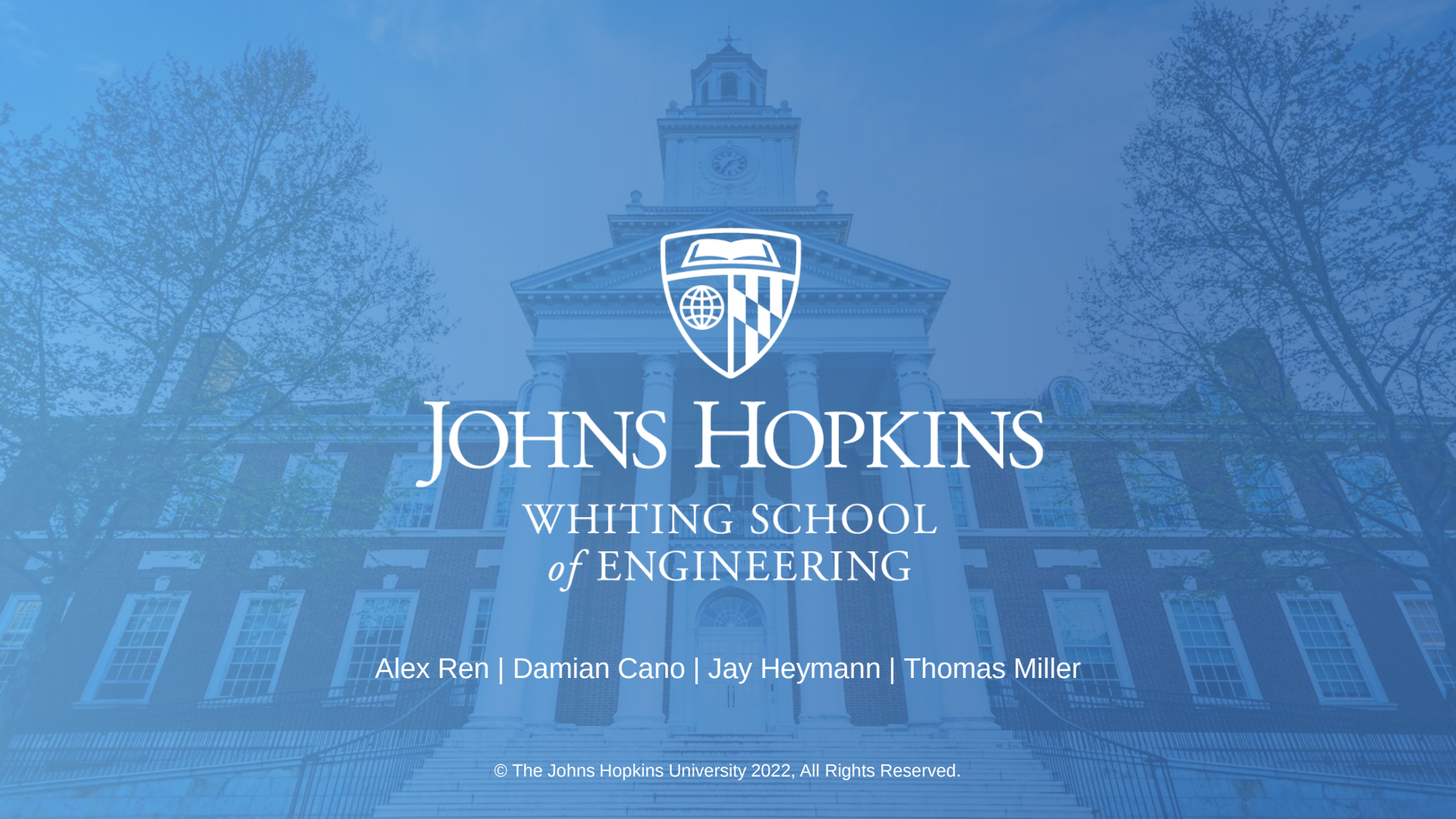
PLGA-PU Hybrid Sponge Unit Cost: **$140.47**

PEG-Coated Sponge Unit Cost: **$8.23**



Conclusion





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