Stool Storage

Developing a user-centered stool management system for ileostomates for healthier and easier living.

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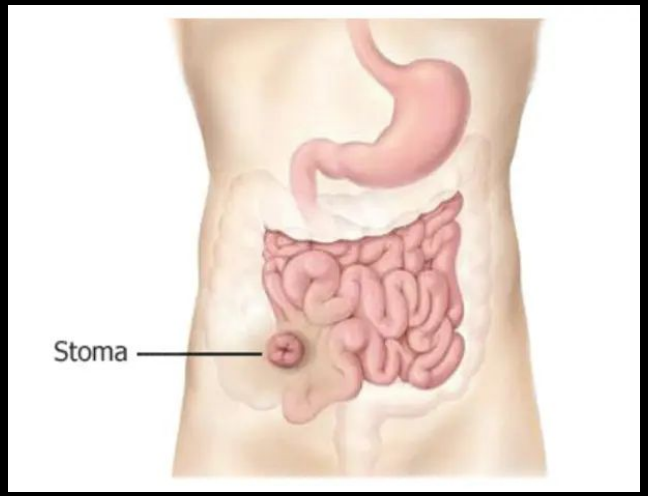
Ileostomies at a Glance



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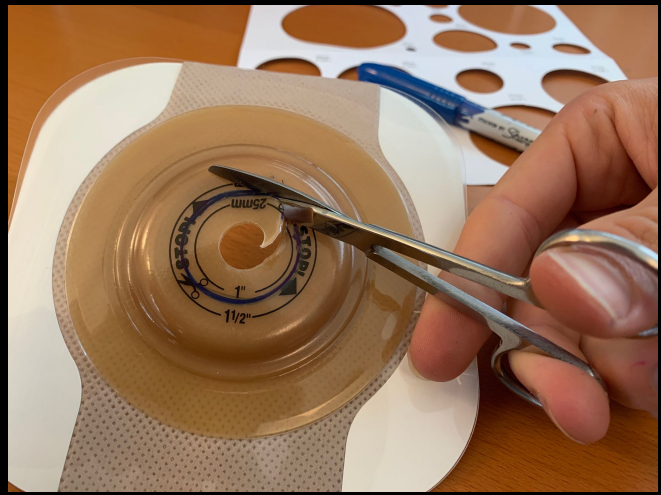


[3]

Ileostomy Management is Inconvenient

[4]

[5]

[6]

Quality of Life Factors

Health

Bags can move and rupture during exercise.

Adhesive seals leak and acidic stool causes irritation.

Travel

The need to change bags is urgent and frequent.

Emptying a bag in public restrooms is hard and unhygienic.

Social

Only 34% of ostomates resumed sexual activity [7].

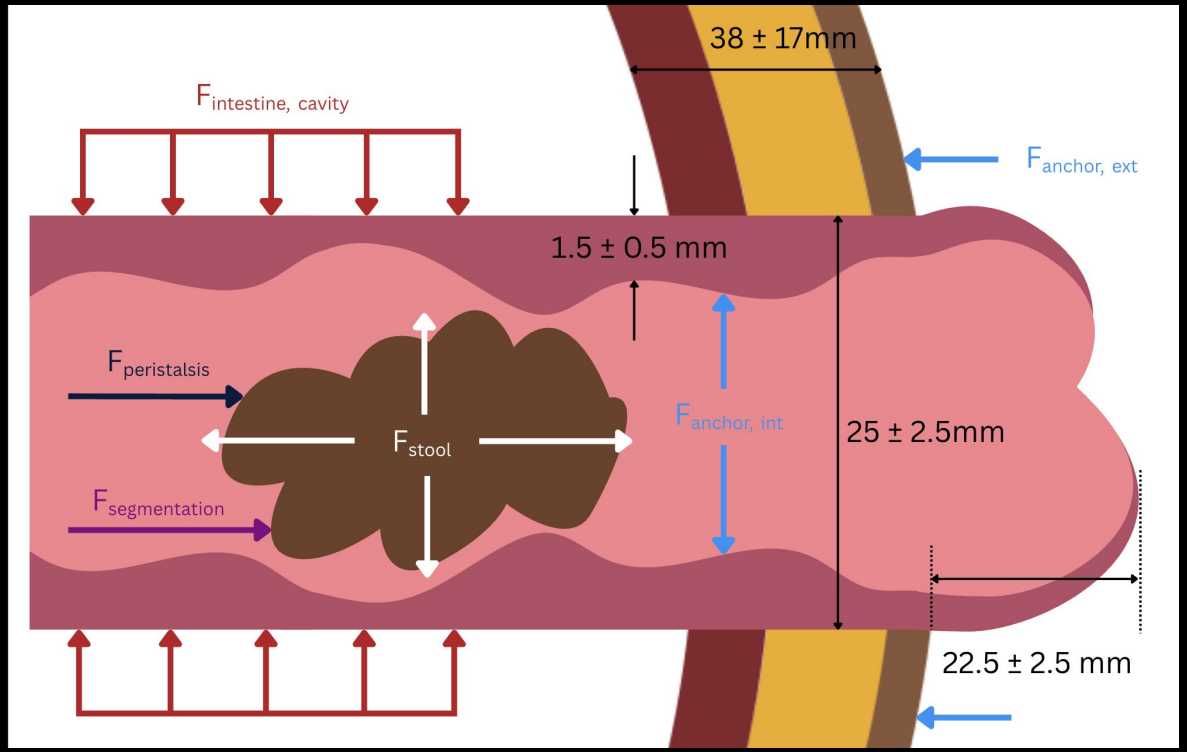
> 50% of ostomates report feelings of depression [8].

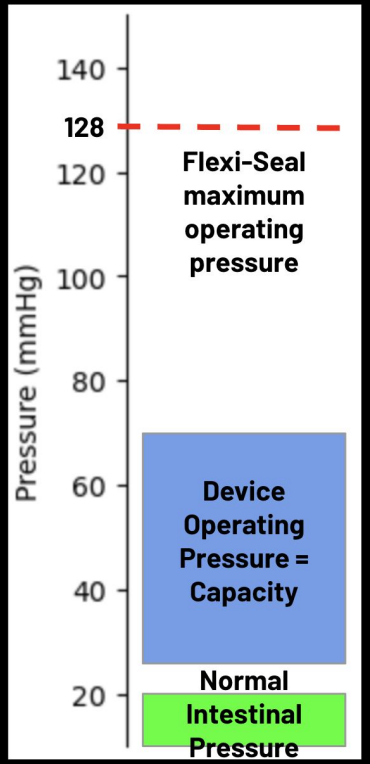
Our Device

A stool management system which allows the user to:

- ➔ Control when stool flows
- ➔ Go for short periods without a bag
- ➔ Change bags quickly, cleanly, and easily
- ➔ Facilitate peristomal healing

Intestinal Environment

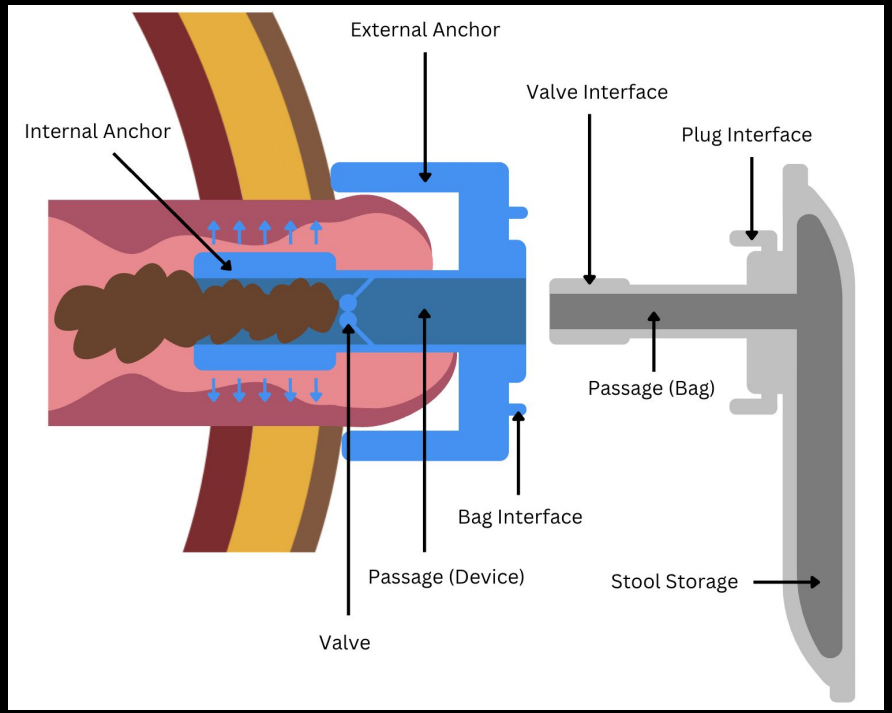




Functional Requirements

Requirement	Value
Leak prevention during normal use	**≥ 20 mmHg** without leakage.
Control of Stool Flow	Opens at **≥ 30 mmHg** external pressure
Safe attachment to body	**20 mmHg** < Pressure exerted on wall < **128 mmHg**
Secure Connection to bag	**≥ 10 N** to detach the bag

Components & Architecture



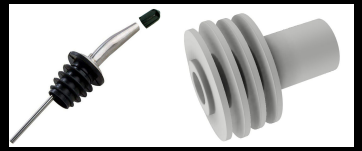
Essentially… a Tap

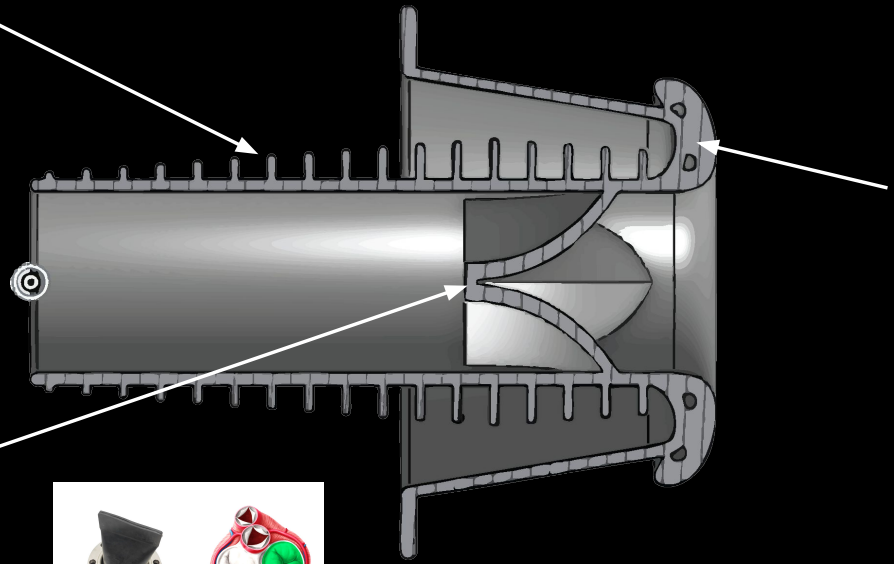
https://www.youtube.com/watch?v=HuqkLIuP7FM

Design Process

Anchoring

How does the device stay in the body?





Valve

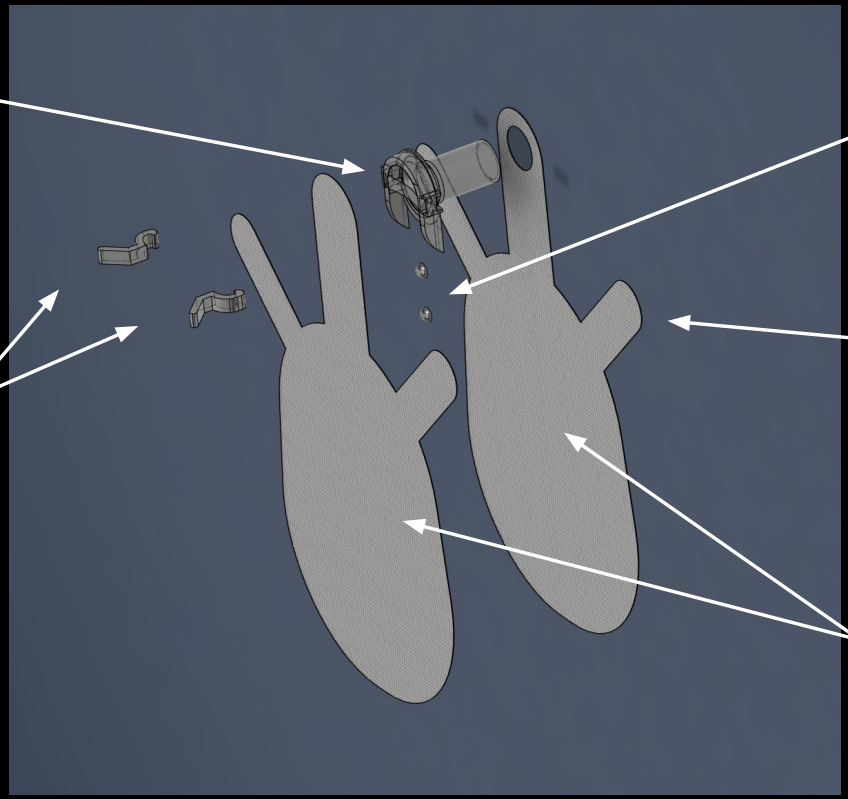
How does the device prevent stool leakage and allow bag insertion?

Quick Connect

How does the bag attach to the device?

Valve Interface

Quick Clips

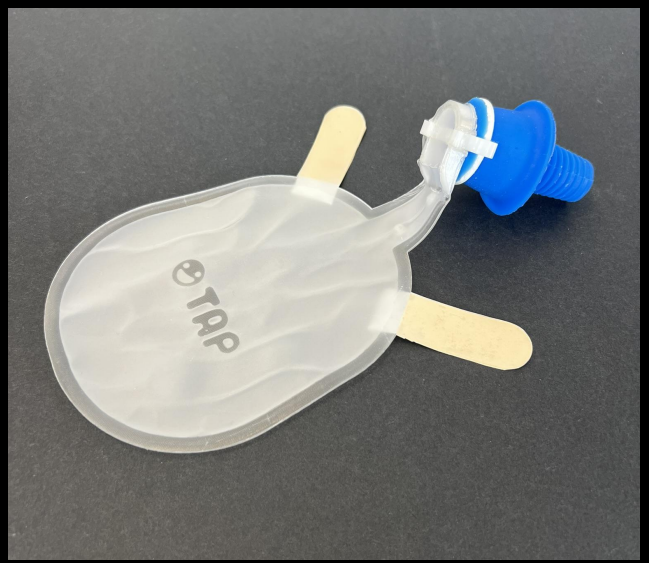


Anti Suction Nubs

Adhesive Strips

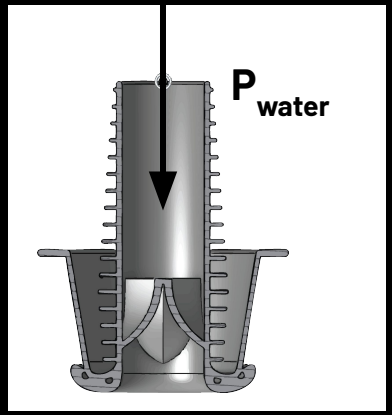
TPU Film Layers

Prototype System



Testing, Results, & Refinement

Valve Leakage Pressure

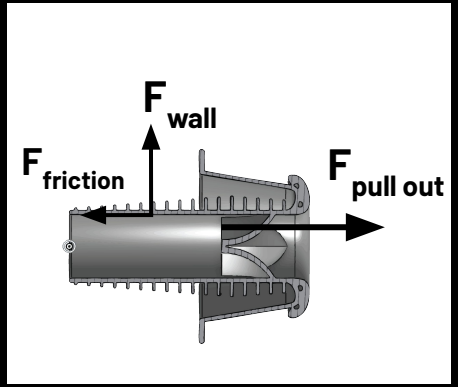


Water applied to seal → pressure at steady state leak stream = fail pressure

Wall Pressure

Distortion of test bed diameter measured → hoop stress calculated ≈ wall pressure

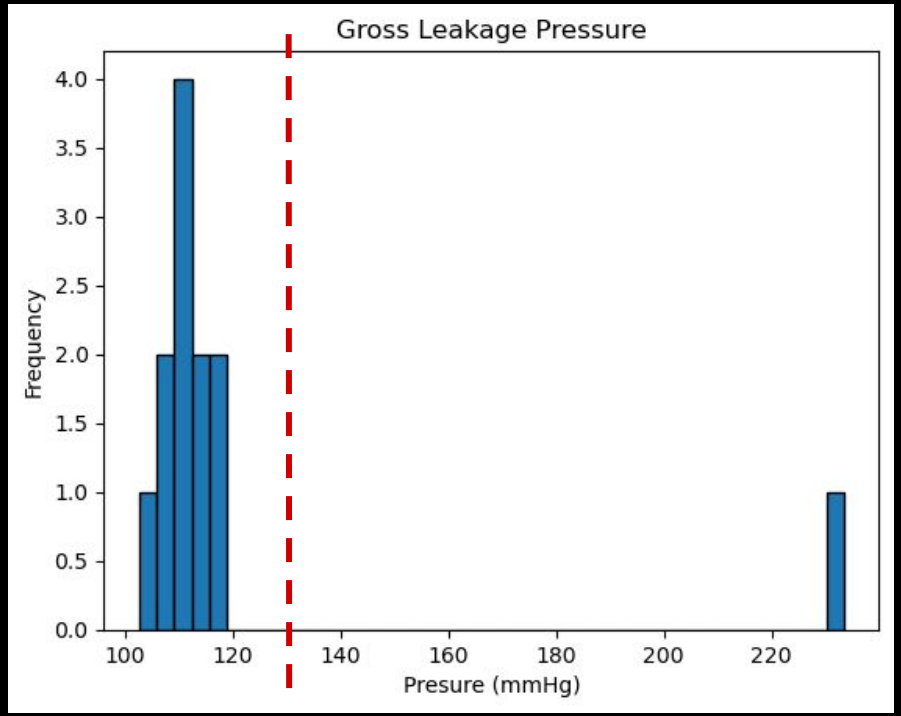
Pull Out Force



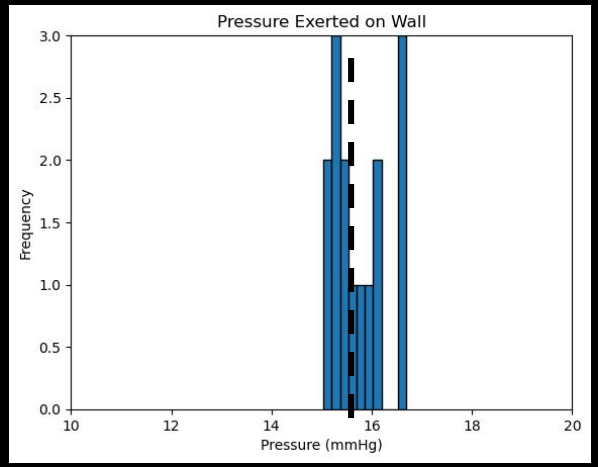
Test bed lubricated with olive oil → Pull Out Force value = max force to remove the device

Valve Leakage Pressure

- Num of Trials: 12 trials
- Applied water column
- Gross leakage defined as steady stream
- **Holds pressure below 128 mmHg**
- **Outlier shows need for more precise fabrication in future models**

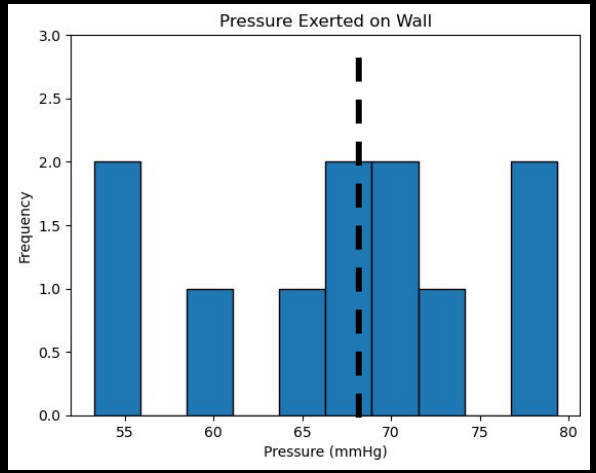


Wall Pressure



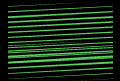
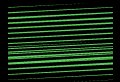
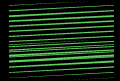
Num of Trials: 15
Average: **15.76 mmHg**
Min: **15.04 mmHg**, Max: **16.69 mmHg**
Distension of intestinal wall is within normal intestinal pressure (10-20 mmHg)

Pull Out Force



Num of Trials: 11 trials
Average: **67.41 mmHg**
Min: **53.28 mmHg**, Max: **79.35 mmHg**
Pullout Force higher than normal pressure (20 mmHg) and less than pressure limit (128 mmHg)

Eval of Functional Requirements

Requirement	Value
Leak prevention during normal use	**≥ 20 mmHg** without leakage. 
Control of Stool Flow	Holds **≥ 30 mmHg** external pressure 
Safe to attach to body	**20 mmHg <** Pressure exerted on wall **< 128 mmHg** 
Secure Connection to bag	**≥ 10 N** to detach the bag

Thank You!
Questions?

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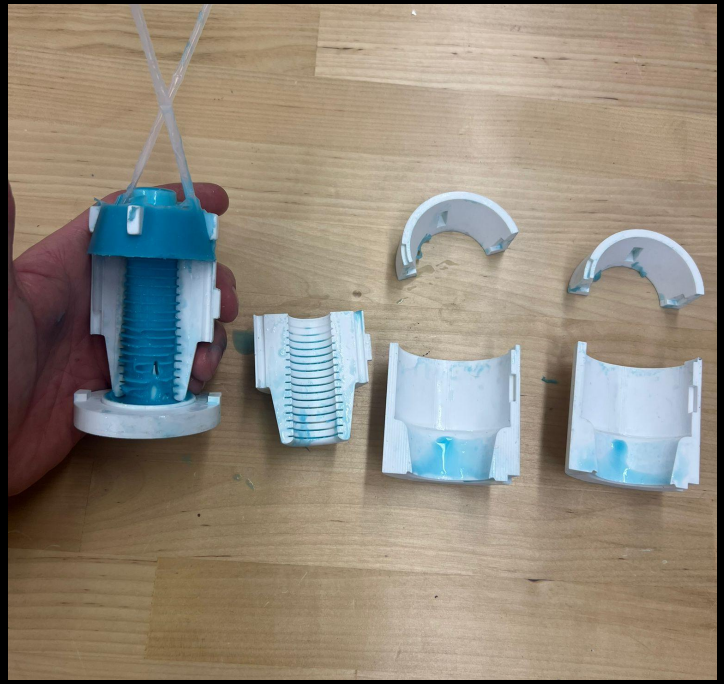
Appendix

The Poop Problem (in Numbers!)

"An estimated **725,000 to 1 million** people are living with an ostomy or continent diversion in the United States, and approximately **100,000** ostomy surgeries are performed each year in the United States" [9]. That's about 1.5x more than the number of people who live in Boston, MA [10].

Fabrication



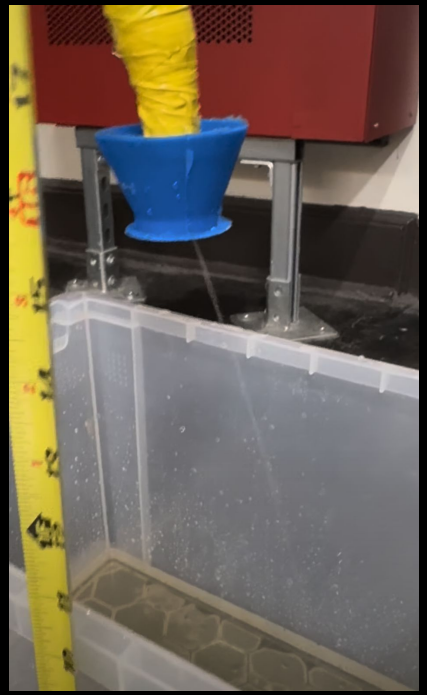
Manufacturing:

- 3D-printed 8 part mold
- Silicone casting w/ comolded ring
- TPU film welding w/ tpu 3d printed valve fittings

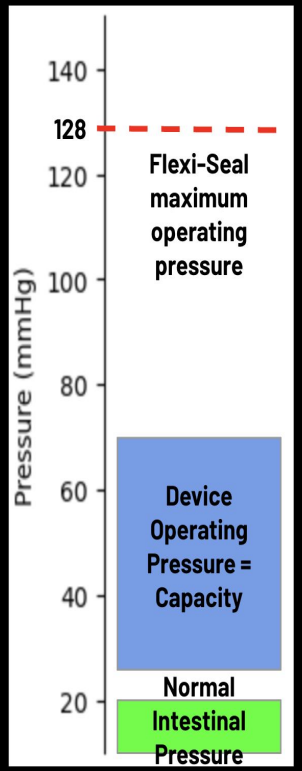
Difficulties Encountered:

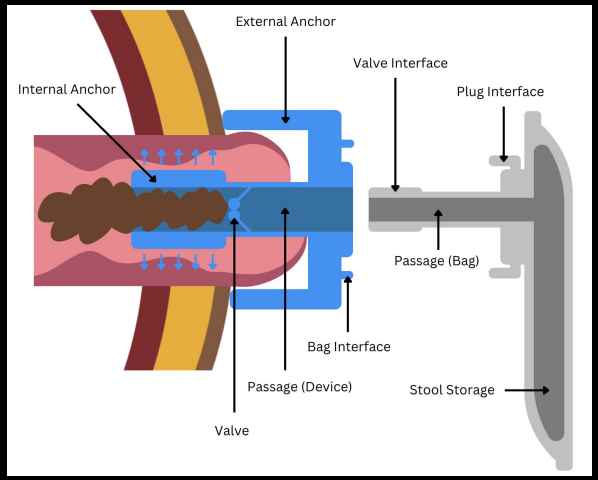
- Mold flow with thin walls / features
- Welding procedures

Valve Leakage Test



Pull Out Force Test





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Device Risks

- Risk Due to User Error:
  - Ischemia
  - Bowel perforation
  - Ulcer formation
  - Mucosal villi necrosis
  - Pressure leaks
- Risk Due to Design:
  - Dislodgement due to anatomical differences
  - Valve rupture
  - Small intestine damage due to insertion and extraction
  - Bowel obstruction

Functional Requirements

Requirement	Definition	Value
Leak prevention during normal use	Valve must remain sealed under normal internal pressure to prevent leakage.	**≥ 20 mmHg** without leakage.
Intentional Valve Activation	Valve opens with only user-inserted cathedral applying sufficient pressure.	Opens at **≥ 50 mmHg**
Maximum Safe Operating Pressure	Ensure safety by staying below tissue damage thresholds.	**< 128.5 mmHg** exerted pressure on wall
Anchoring Stability	Internal fins must resist dislodgement from peristalsis and movement.	Pullout force ≥ **5N**