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System for Enhanced Removal of Gastrointestinal Clots

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System for Enhanced Removal of Gastrointestinal Clots

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Project Background

Gastrointestinal Bleeding (GI Bleeding/GIB)

- Major clinical condition, not a disease, but a symptom
- Results in over 400,000 hospital admissions annually
- Causes include: peptic ulcer, hemorrhoids, tears or inflammation in the esophagus, diverticular disease, inflammatory bowel disease, tumors, colon polyps, proctitis, ulcerative colitis

Diagnosis

- Endoscopy/colonoscopy
- CT angiogram
- Radionucleotide imaging

Treatment

- Intravenous administration of proton pump inhibitors (PPIs)
- Use of embolic agents
- Targeted endoscopic treatment



Project Background

Endoscopes and GI Bleeding

- Gastroscopes and colonoscopes used for examining the upper GI tract and colon (diagnosis and identifying source of bleeding)
- Specialized therapeutic endoscopes have larger instrument channel diameters → allow for more complex accessories (treatment)
 - Hemostatic forceps that pinch blood vessels
 - Heater probes to cauterize bleeding sites to induce hemostasis
 - Water valves/jets/nozzles and suction pumps

Endoscopy Procedure

- Flexible tubing is inserted either through the mouth or intranasally
- Patients are sedated (general or local anesthesia) and typically do not report pain

Project Background

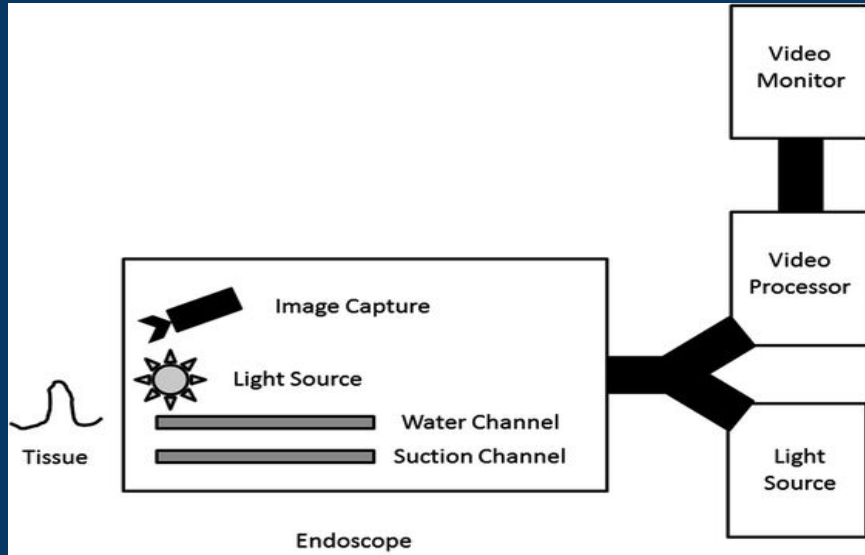


Figure 1: Basic schematic of endoscope system

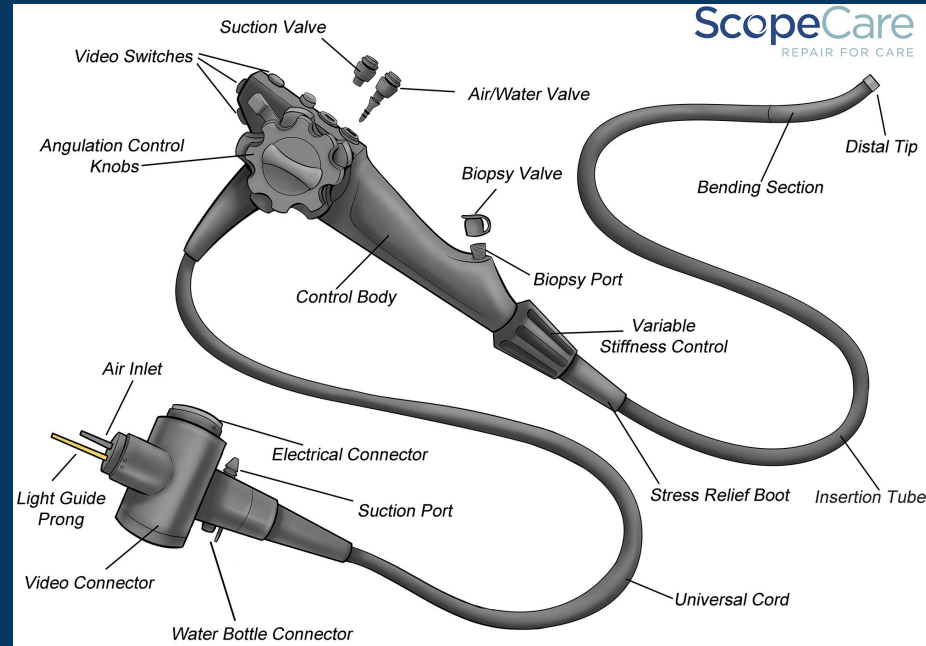


Figure 2: Current endoscope device

User Needs Statement

- Safe and efficient GI clot removal device during surgeries
- Device must not damage, rupture, perforate, and/or abrade any organs it comes into contact with
 - Must be able to fit within the accessory channel of a standard endoscope and travel through the GI tract with ease and flexibility
- Should be able to mechanically break and aspirate blood clots in the GI tract at a reasonable rate without clogging the device
- Should be easy for physicians to use, requiring little additional training or controls from that of a standard endoscope
- Device must be biocompatible and not present any further harm to the patient
- Device must be disposable in order to reduce the risk of cross contamination



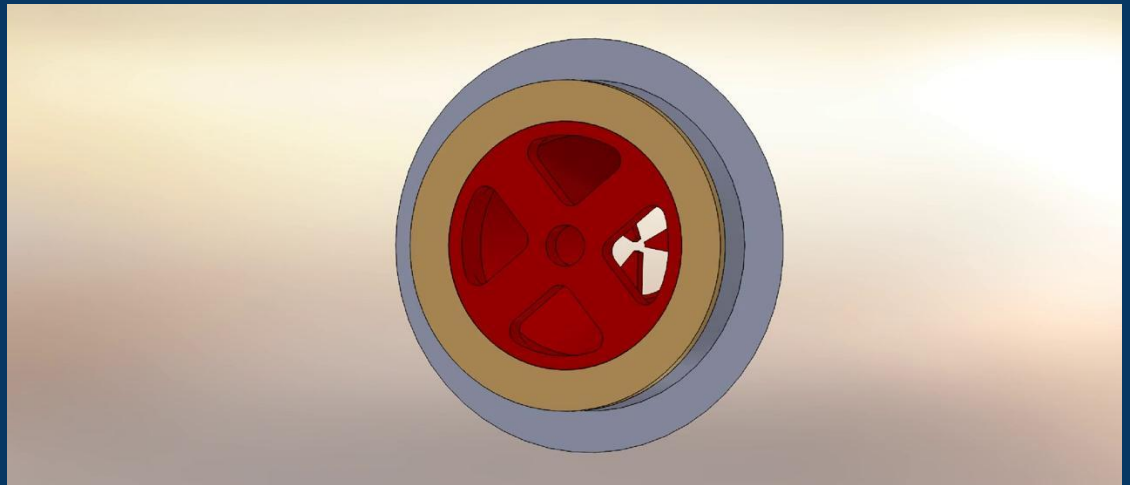
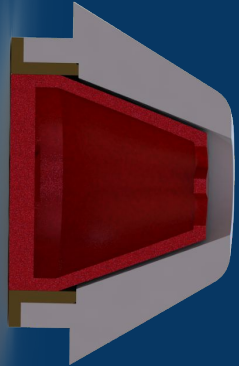
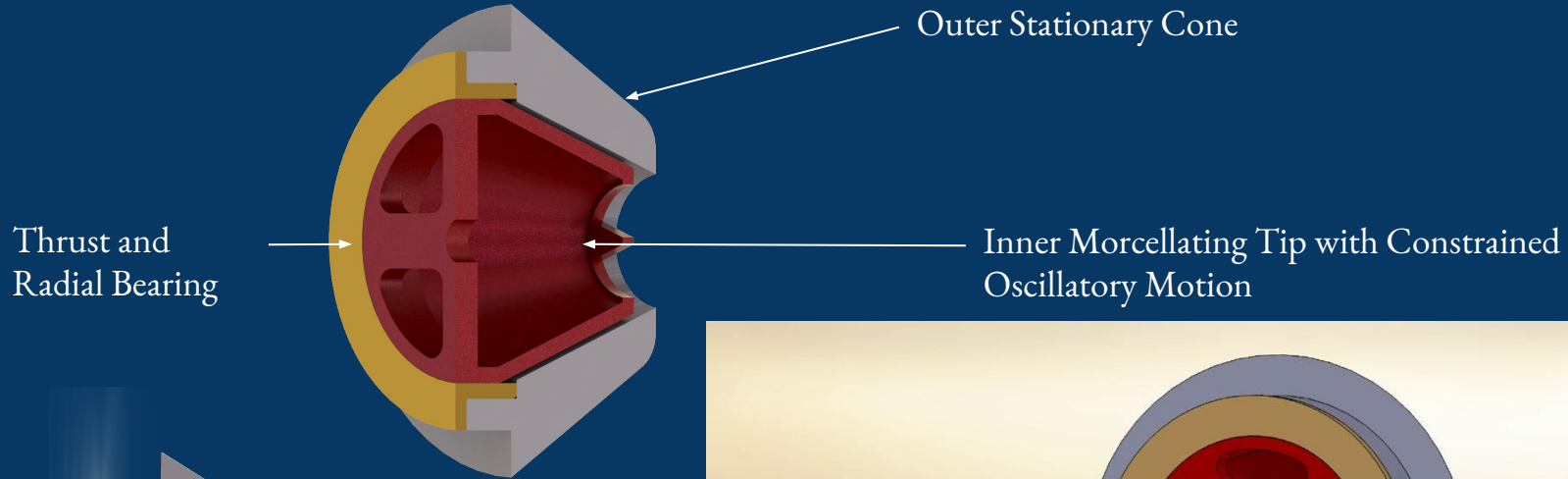
Concept Selection Method

Ranking Number	Explanation
1	Inadequate Solution
2	Poor Solution
3	Adequate Solution
4	Good Solution
5	Ideal Solution

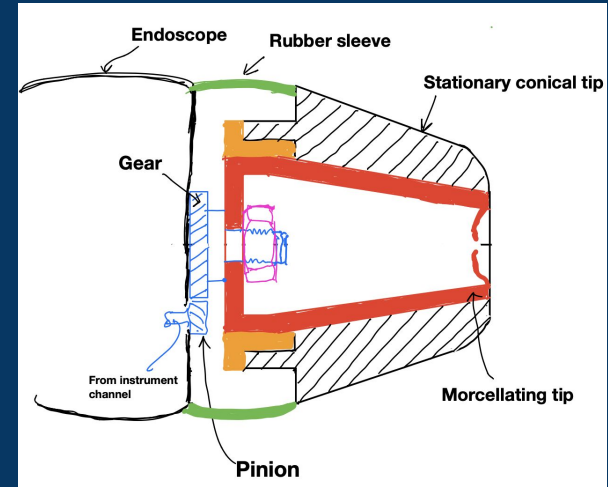
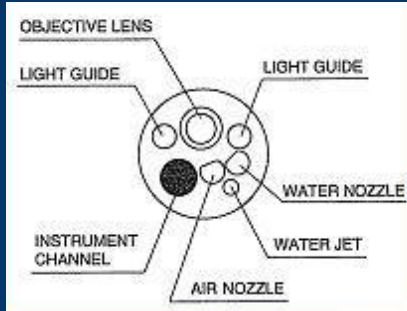
Criteria	Weighting	1. Pressure Sensor		2. Mini Fan		3. Conical Evacuator	
		Score	Value	Score	Value	Score	Value
Risk to the Patient	0.25	4	1.0	3	0.75	5	1.25
Ease of Use	0.1	3	0.30	4	0.40	4	0.40
Effectiveness	0.25	4	1.0	3	0.75	4	1.0
Affordability	0.1	1	0.10	2	0.20	4	0.40
Biocompatibility	0.15	3	0.45	4	0.60	4	0.60
Comfortable Size	0.15	2	0.30	2	0.30	4	0.60
Total		3.15		3.00		4.25	



Detailed Design - Prototype



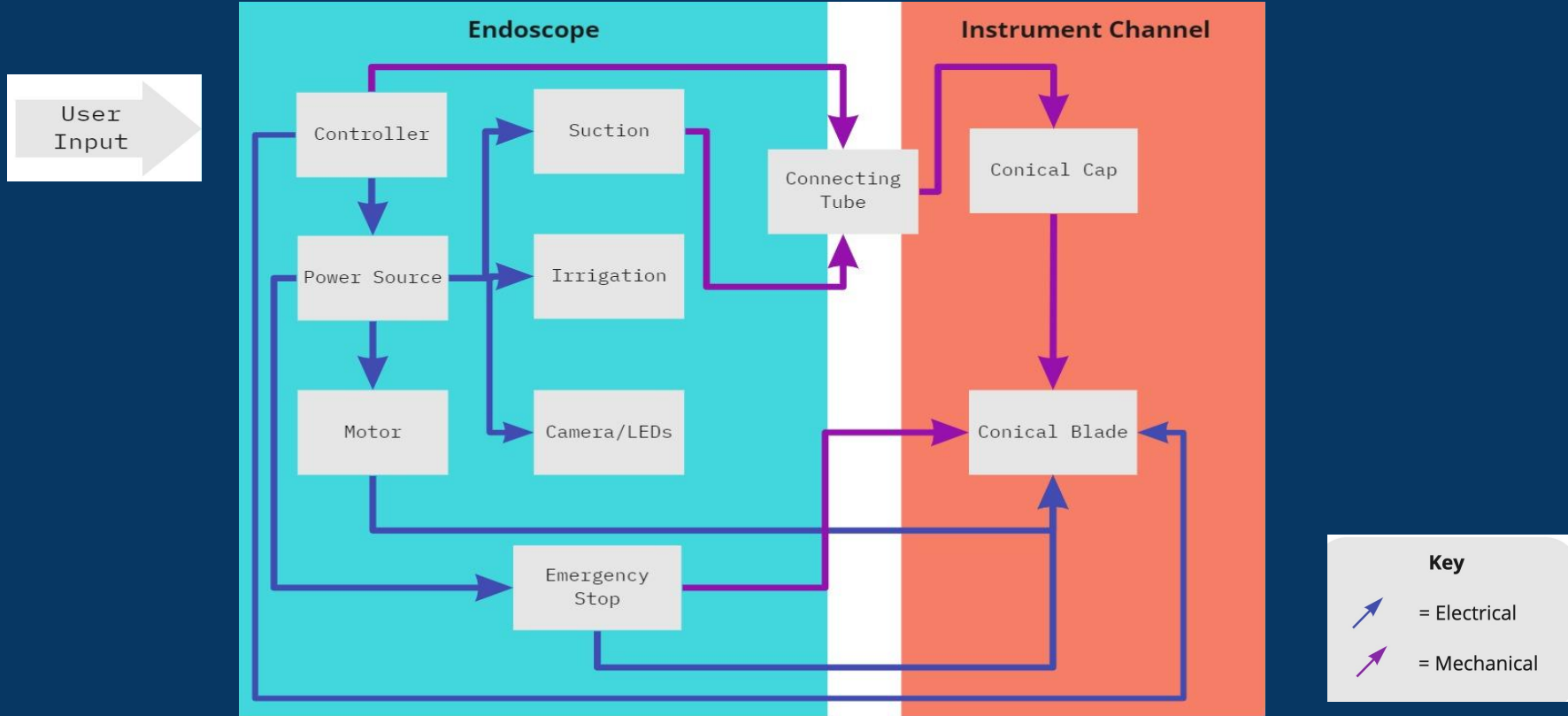
Detailed Design - Integration of Endoscope



Drive shaft of Conical Evacuator
 Placed in Existing Endoscope
 Instrument Channel

Conical Evacuator Device Attaches to Distal
 End of Endoscope

System Architecture



Future Design Plans

- Further development of the placement and connection of the conical blade to the endoscope
- Investigation into the addition of a sleeve component to add irrigation, suction, and bristles
- Possible extension of the scope to include colonoscopy procedures
 - The device would need to dislodge and break up stool
 - Stool is tougher and more fibrous than blood clots

Future Validation & Verification Plans

- Basic Function Specifications
 - 2 Proposed Verification Plans
 - Ensure Length & Diameter meet Technical Specifications
- Design Specifications
 - 14 Proposed Verification Plans
 - Cost, bending, weight, etc
- User Specifications
 - 3 Proposed Verification Plans
 - Oscillation, continuous use, ease of operation, etc
- Safety Specifications
 - 4 Proposed Verification Plans
 - Ensure emergency off switch, oscillation, cleaning, etc

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