SURGICAL STAPLER FOR ANASTOMOSIS SURGERY

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Background

- There are over 600,000 colon surgeries performed each year in the US, with 100,000 new cases of colon cancer per year.[1]
- Current technique to perform an anastomosis involves suturing a segment of the colon around the stem of the anvil via the purse string technique. [2]
- This connects the anvil to the circular stapler to join and seals the two colon ends. [2]
- Purse string technique does not enable a tight fit around the stem of the anvil resulting in poor anastomosis and leak rates increasing by 15%. [3]
- Our team is proposing a new design to Endo Gia Universal Stapler with modifications addressing these issues.

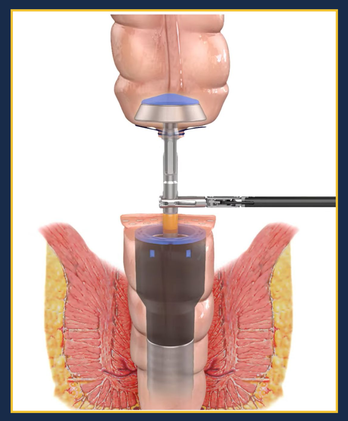

Figure 1: Anastomosis technique. [4]

Objectives

1. To design a surgical stapler that can clamp around the anvil.
2. To design a surgical stapler that can staple colon tissue around the anvil.

Device Design & Prototyping Methods

- A 3.6mm radius notch is introduced within the lower jaw to capture the anvil at any location along its length.
- A portion of the blade is removed to prevent it from obstructing the anvil
- The top jaw is designed to prevent staple ejection at the anvil location.
- The blade will be SLA printed using flexible 50A resin.
- The bottom jaw will be machined from aluminum, and the top jaw will be 3D printed.

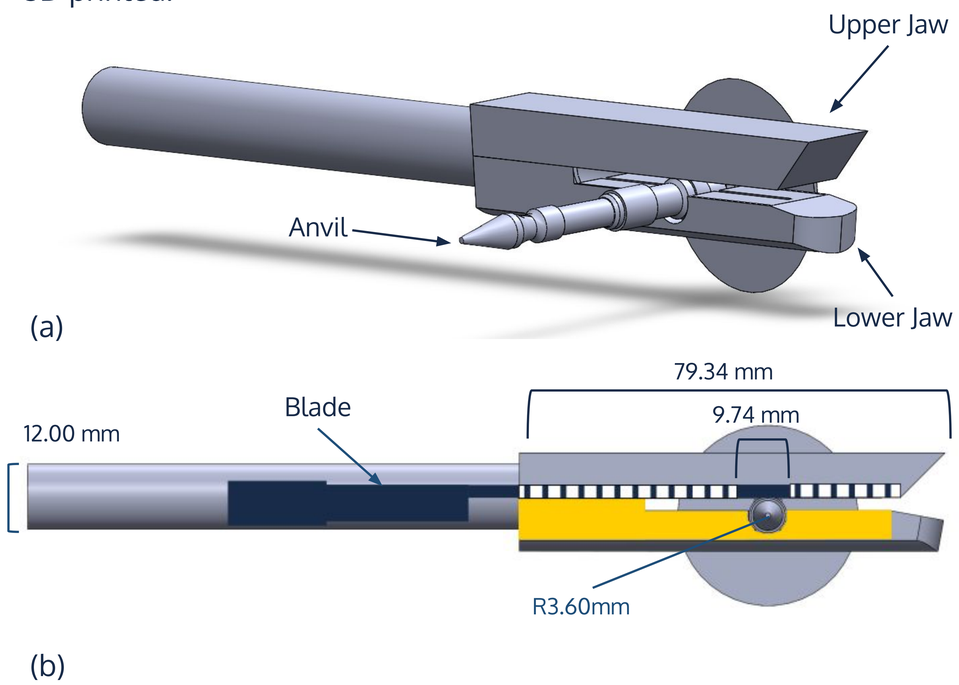

Figure 2: (a) Surgical Stapler 2.0, (b) Changes to Design

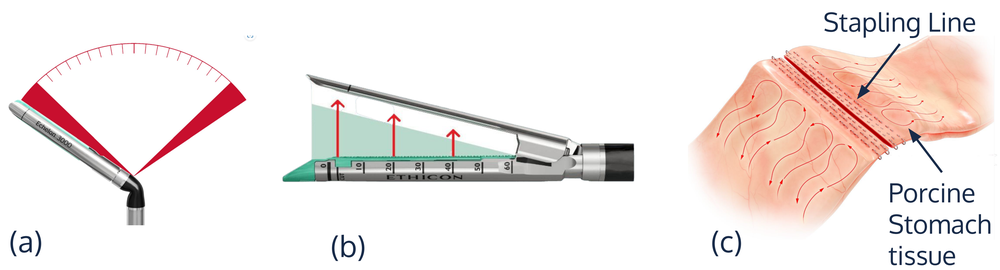

Figure 4: (a) Device articulation[8] (b) Jaw aperture[8] (c) Staple Line[8]

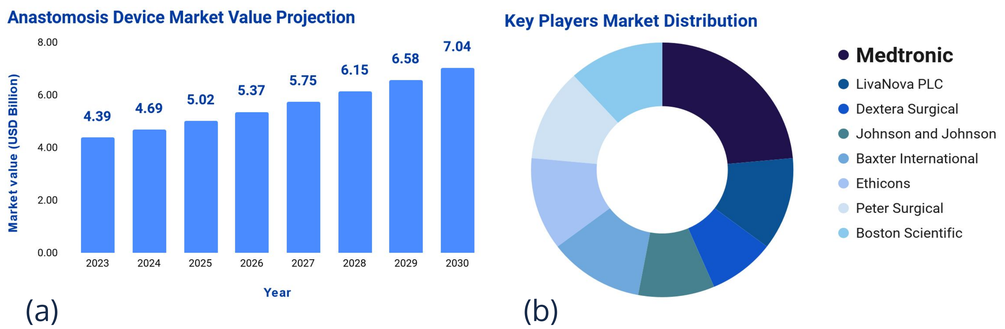

Figure 5: (a) Anastomosis Devices Market Analysis [5] (b) Market Share Insight.[6]

Testing Plan	Expected Results
Mechanical Testing	
To ensure the jaw can be pivoted at different angles and wide enough to grasp thick tissue.	Jaw Articulation:48.91°T Jaw Aperture: 18.75 mm
Leak Testing	
To evaluate the quality of the seal by measuring the water pressure needed to induce a leak.	Leak Pressure: 66.8± 27.2 mmHg
Stapling Testing	
To test the stapling consistency through the ratio of malformed staples.	Stapling Testing: <1.4% malformed staples on 4mm tissue

Market Analysis

- 7% annual growth rate driven by the increased prevalence of cancer and age.[6]
- The disposable segment of the surgical stapler accounted for 88% of revenue share in 2021.[7]
- Fragmented market with no dominant player indicating a true unmet need.

Regulatory Pathway

- FDA 510k Class II device approval process.
- Risk management: ISO 14971:2019.

Acknowledgements

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