

Automated Uretero-Intestinal Anastomosis with Absorbable Staples – Stapler specific PDS

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Problem Statement:

In patients with bladder cancer, the bladder can be either partially or completely removed. A procedure called a radical cystectomy is required to completely remove the bladder when cancer has invaded the muscle layer of the bladder. Afterwards, a section of the small intestine can be used to form a new bladder (neobladder). If the neobladder is not constructed, a ureostomy bag is implemented instead. However, in both procedures the ureters must be connected to the new bladder tissue; this is currently done using absorbable sutures. There are several complications associated with this approach due to the invasiveness and length of the procedure. Our goal is to design and construct a stapler that is small enough to be passed through the ureter to perform automated uretero-intestinal anastomosis and secure the ureters to the neobladder or ureostomy bag with absorbable staples.

Client requirements:

- Must be usable for laparoscopic surgery
- Stapler head must be able to fit through a trocar (i.e. must be less than 1 cm in diameter)
- Must be able to pierce and cut a circular opening in the neo-bladder
- Firing mechanism must be simple to operate
- Must be faster and more consistent than suturing the tissues together
- Must be sterilizable
- Body of stapler must be reusable with staple cartridges that are for single use
- Must form a water-tight seal of the ureter to the neo-bladder

Design Requirements

1. Physical and Operational Characteristics

- a. *Performance requirements:* Will be used to perform automated anastomosis to secure two ureters to a neobladder with absorbable staples. Will be used for multiple surgeries and must have cartridges to re-load staples between uses. Must be sterilizable.

- b. *Safety*: Must not damage surrounding tissue in the abdominal cavity, bladder or ureters. Must create a secure water-tight seal with both ureters to allow for normal use of the kidneys post-surgery.
- c. *Accuracy and Reliability*: Must accurately deliver two concentric rings of staples to secure the ureters to the neo-bladder. The seal created must be water-tight.
- d. *Life in Service*: The firing mechanism is intended to be used for multiple surgeries. Ideally, the firing mechanism should be functional for at least one hundred uses.
- e. *Shelf Life*: There are no degradable components to the stapler portion of our design. Theoretically the stapler should have an indefinite shelf life when properly stored.
- f. *Operating Environment*: The device will be operated in an operating room. It must be sterilized before use.
- g. *Ergonomics*: Should be easy to operate by one experienced surgeon. The device will need to fire with a single hand so that the other hand may be used to stabilize the surrounding tissues. Must be faster and more consistent than suturing the tissues together.
- h. *Size*: The stapler head must be able to fit through a trocar having a diameter of 1 cm. It must be less than 0.7 cm to fit within the spatulated ureter. The neck of the stapler must be long enough to fit through the trocar, neo-bladder, and ureter in laparoscopic surgery. This equates to approximately 30 cm.
- i. *Weight*: The device should be easy to operate using one hand during laparoscopic surgery, and thus should not exceed 5 lbs.
- j. *Materials*: The material used should be biocompatible. It should not pit or rust, and should be sturdy and maintain its shape. Ideally, the neck should be made of a flexible material. The final product head should be metal so that staples may be fired without risk of deforming the firing mechanism.
- k. *Aesthetics, Appearance, and Finish*: Aesthetics are not a priority but the stapler should appear professional. The stapler should be free of sharp edges.

2. Production Characteristics

- a. *Quantity*: 1 deliverable.
- b. *Target Product Cost*: Up to \$500.

3. Miscellaneous

- a. *Standards and Specifications*: Must be approved for safety and function by the surgeons utilizing the device. Must have IRB approval once used in humans with absorbable staples.
- b. *Customer/Patient related concerns*: Must create a water tight seal after anastomosis is performed. Must not do damage to any other tissues in the body.
- c. *Competition*: There is currently no product made specifically for sealing the ureter to the neo-bladder during anastomosis. There is a similar product on the market for securing the colon together after a section has been removed due to disease, however this device is far too large to be used for reconnecting ureters to a neo-bladder.