Automated Uretero-intestinal Anastamosis with Absorbable Staples

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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 need to 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 staples. In addition to fabricating a stapler, we will be responsible for designing and testing new materials to be used for biocompatible, absorbable staples. The tasks of this project will be divided over two semesters, we will be working on designing the stapler first semester and the staples second semester.

Client requirements:

- Head needs to be 1.5 cm in diameter
- Needs to be able to pass through the neo-bladder to perform anastamosis
- Must be simple to operate with a single motion required to fire staples
- Must be faster for experienced surgeons to operate than tying sutures
- Must be sterile
- Can be reusable or one-time use if comparable in price to other similar products on the market for other procedures
- Must create a water-tight seal of the ureter to the neo-bladder
- Must be usable for open surgery
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Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: Will be used for a single patient to perform automated anastamosis to secure two ureters to a neobladder. If product

can be autoclaved, it could be used for multiple patients. If being used for multiple surgeries, stapler must have a mechanism to re-load staples between uses.

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 staples to secure the ureters to the neo-bladder. The seal created must be water-tight.

d. *Life in Service*: The device is intended to be single use, but if its materials can be autoclaved could potentially be used for multiple patients.

e. *Shelf Life*: There are no degradable components to our design. Theoretically the device should have an indefinite shelf life when properly stored.

f. *Operating Environment*: The device will be operated in a hospital. It needs to be sterile to avoid cross-contamination. It will be disposed of after being used unless it can be autoclaved and sterilized.

g. *Ergonomics*: Should be easy to operate by one experienced surgeon.

h. *Size*: The head of the device (and thus diameter) must be smaller than 1.5 cm to fit within the spatulated ureter. The entire device must be long enough to fit through the neo-bladder and ureter in an open surgery.

i. *Weight*: The device should be easy to operate inside a body during open surgery, and thus shouldn't exceed 2-5 lbs.

j. *Materials*: The material used should not pit or rust easily. It should be sturdy and maintain its shape. It should not be magnetic to avoid any unintended reactions in the operating room.

k. *Aesthetics*, *Appearance, and Finish*: Aesthetically pleasing. Appearance isn't really an issue, it should be free of rough edges and sleek for safety.

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 anastamosis is performed. Must not do damage to any other tissues in the body. As a second step in this project, the staples should degrade within 30 days to mitigate the risk of infection and pain in the patient.

d. *Competition*: There is currently no product made specifically for sealing the ureter to the neo-bladder duing anastamosis. There is a similar product on the market for securing the colon back 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.