

# **Automated Uretero-intestinal Anastomosis with Absorbable Staples – Staple 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 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:**

- Need to be completely absorbable to allow for full tissue healing and regeneration
- Need a form a water tight seal on the intestine-ureter linkage
- Need to be biocompatible – no immune reaction
- Must be able to withstand the caustic environment of the ureter when it is filled with urea.
- Must hold their shape
- Must be strong/sturdy but flexible enough to be bent
- Must work in conjunction with the stapler

## **Design requirements:**

### **1. Physical and Operational Characteristics**

- a. *Performance requirements*: Will be used with the stapler for a single patient to perform automated anastomosis to secure two ureters to a neobladder.
- 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. Must not cause infection or immune response.
- c. *Accuracy and Reliability*: The seal created must be water-tight.
- d. *Life in Service*: Will be single use, eventually will degrade in vivo.
- e. *Shelf Life*: Unknown – should be used within one month after they are fabricated to avoid any leaching or degradation outside of the body.
- f. *Operating Environment*: The device will be operated in a hospital. It needs to be sterile to avoid cross-contamination.
- g. *Ergonomics*: Should be simple to insert into stapler via a staple cartridge into which the staples will be pre-loaded.
- h. *Size*: The staples will be shaped like a rectangle missing one side. The base will be 3mm wide and the legs will be 7mm long. The entire staple will be 0.5mm thick.
- i. *Weight*: Negligible, in the ballpark of 1mg.
- j. *Materials*: The final material will be composed of degradable polymers, such as PCL and PLA, in ratios that will be optimized using testing.
- k. *Aesthetics, Appearance, and Finish*: Should have sharp points at the ends of the legs to allow them to puncture tissue.

## **2. Production Characteristics**

- a. *Quantity*: At least 12 deliverables, we plan on making these in bulk for testing using injection molding. A total of 12 staples will be necessary to fill a cartridge.
- b. *Target Product Cost*: Undetermined, up to \$0.10/staple

### 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.

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. As a second step in this project, the staples should degrade eventually to promote tissue healing and regeneration.

d. *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 sealing epidermal incisions, this product is sold by the *Insorb*© corporation.