Product Design Specifications

Client requirements:

- Head needs to be less than 10 mm in diameter
- Needs to be able to pass through the neo-bladder to perform anastomosis
- Must be simple to operate with a single squeezing motion required to fire staples
- Must be faster for experienced surgeons to operate than tying sutures
- Must succeed in delivering a staple line that is consistent across multiple procedures
- Must be sterile
- Can be reusable or one-time use if comparable in price to other similar products on the market for other procedures (ie the Ethicon endo-stapler for colorectal anastomosis)
- Must create a water-tight seal of the ureter to the neo-bladder
- Must be usable for open surgery

Design requirements:

1. **Physical and Operational Characteristics**

   a. *Performance requirements*: Will be used for a single patient to perform automated anastomosis which secures 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 function 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. Repeatable results across procedures is important.

   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 prior to use 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 10 mm to fit within the spatulated ureter. Additionally, the head of the device may vary in size depending on the size of the ureter in the patient. 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*: Device should be aesthetically pleasing, sleek and free of rough edges that could damage tissue unintentionally during the procedure.

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. 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 during anastomosis. 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.