

**“Absorbable Staples for Anastomosis” – Tong Competition Executive Summary**  
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Bladder cancer is the fifth most common cancer in the United States. The National Cancer Institute estimates that in 2012 over 73,500 new cases of bladder cancer will be reported and nearly 15,000 people will die from this disease [1]. When cancer cells invade the bladder muscle, the desired treatment is a radical cystectomy, surgical removal of the bladder. A neobladder is formed from a portion of the intestine, and the ureters are attached to it with absorbable sutures. Because the surgeon must suture the ureters in a small working area, the procedure is time consuming, and the quality of the attachment is dependent on the skill level of the surgeon. We have developed absorbable staples compatible with a circular stapler that will promote anastomosis, decrease procedure time, and translate into fewer complications for patients.

There are currently no absorbable surgical staples on the market designed for abdominal surgeries. Insoorb manufactures an absorbable staple comprised of 63:37 poly(lactide-co-glycolide) (PLGA) designed for subcutaneous skin closure. Staples fired in a linear fashion have a barb on the end of each leg designed to bring together the two sides of the skin wound, enabling healing. Ethicon sells a circular stapler used in colorectal surgeries that fires titanium staples. Metal staples are not suitable in the acidic bladder environment as they may cause kidney stones. The stapler is also too big for some applications in the abdominal cavity, including uretero-intestinal anastomosis.

Compared to the Insoorb staples, our staples are made of 85:15 PLGA, a material generally accepted by the Food and Drug Administration (FDA) for use in medical devices. Our staples should degrade after approximately 60 days, as projected by this ratio of PLA to PGA, which is greater than the minimum degradation time of 30 days specified by our client. Our staples have three barbs on each leg to enhance the anastomosis of the ureters to the neobladder by gripping the tissue together as it heals. The dimensions are also much smaller than the Insoorb staples.

We performed degradation and mechanical testing on test specimens made of the staple material in solutions of pH 4.5 and pH 8, which is the range of pHs found in the bladder. At day 0, 10, and 19, we removed the staples and performed a tensile test in accordance with ASTM D638-10. These tests indicated that the mechanical strength of the rigid, absorbable staples is comparable to the absorbable sutures and that the staples will maintain their strength for at least 20 days. According to our client, this is enough time for the tissue to heal significantly.

Our absorbable staples can be applied to a number of anastomosis surgeries such as those in the gastrointestinal tract, blood vessels, or the urinary tract. With an appropriate firing mechanism, the staples will offer the opportunity to minimize operative times and subsequent interventions as well as reduce inconsistencies between surgeons.

## References

- [1] Bladder Cancer. *National Cancer Institute*. Retrieved April 18, 2012, from <http://www.cancer.gov/cancertopics/types/bladder>.