

EXECUTIVE SUMMARY

New Product Concepts to Restore Urinary Continence Post-Prostatectomy

Imagine you are a 70-year-old man who recently underwent a radical prostatectomy after being diagnosed with prostate cancer. Post-prostatectomy, when you are relieved the ordeal is over, you uncomfortably find that instead of having difficulty voiding, you are constantly wetting your pants, in public, at home, and at night in bed. You cannot control your bladder, and your bladder is beginning to control you.

For a quarter of the patients that urologist Dr. William Brant sees, “the discomfort of being incontinent post-prostatectomy, even with the implementation of a device to restore urinary continence, makes them wish they had never had their prostate removed.”¹ This need led to our core question: how might we develop better products to restore urinary continence in post-prostatectomy males?

American Medical Systems’ final deliverable is a product concept paper including:

1. Final Patent Disclosure for the adjustable sling concept
2. Prototypes and benchtop testing for the adjustable sling
3. Investigation of the male SUI solution space and a comprehensive set of alternatives
4. Three concepts based on key specifications, technical feasibility and IP-defensibility
5. Germane insights from voice of the physician research
6. Identification of the pathophysiology of post-prostatectomy urinary incontinence
7. Recommendations for further development of the three concepts

Since the Critical Design Review, we pushed the design development and testing of the adjustable-ratchet sling concept, as well as explored two alternative concepts: an electronic artificial urinary sphincter, and a urethral lengthening device. This effort shows significant outcomes. After presenting our concepts, AMS is already moving forward with the electronic sphincter. We also collected a comprehensive literature review correlating diminished urethral length and increased urinary incontinence. This alternative concept is an implantable device during prostatectomy. Finally, we have prototyped, tested, and submitted a final patent disclosure for our adjustable sling concept.

The adjustable ratchet sling concept uses the standard sling as a baseline approach for balancing retention and continence, and provides post-operative adjustability to maintain optimal tension and adjustment. Ideally, adjustment can be done without an incision using magnetic manipulation of the ratchet mechanism.

Testing was completed to verify this prototype satisfactorily met our design specifications. Tests include: efficacy flow test, adjustment test, ratchet torque test, sling base force test, magnetic strength tests, pawl stress and displacement tests, and an FMEA analysis.

Conclusively, we successfully completed the goals laid out at the beginning of the project and closely followed our GANTT chart throughout the process. We are confident that our deliverable has exceeded AMS’ expectations, and that we are delivering value to our sponsor.

¹ Brant, Dr. William. SUI Expert Interview. Natalie Afonina and Lorin Paley. 14 October 2014