



**Project Name:** Intraluminal Gastroplasty Device  
**Application:** Endoscopic Treatment for Obesity  
**Customer:** Safestitch Medical  
**Website:** <http://safestitch.com>



## AN ENDOSCOPIC TOOL FOR THE TREATMENT OF OBESITY

### BACKGROUND AND PROJECT CHALLENGE

Obesity is a problem that affects roughly 40 Million people in the United States. A recent study states that 17% of the US medical costs can be attributed to obesity – \$168 Billion/year. One conventional treatment for obesity is to drastically reduce the size of the stomach (gastroplasty) to reduce the amount that people can eat. PADT worked with Safestitch Medical to develop a transoral system that could provide a gastroplasty and avoid the conventional open procedure.

### PROCESS AND SOLUTION

Our initial work involved a thorough conversation about product requirements combined with a series of conceptual designs. Very quickly in this process it was clear that there were some basic unanswered questions about the behavior of the stomach tissues when subjected to various events such as suturing or gripping via suction. We answered these questions with a series of verification tests. In this testing process, we designed simple surrogates that mimicked concepts that we had developed for the actual hardware. These surrogate test components were manufactured quickly with PADT's in-house prototyping capability. Both Stereolithography (SLA) and Selective Laser Sintering (SLS) were used to manufacture these surrogates. The result was that we were able to quickly test many potential design configurations and downselect promising approaches.

PADT's development philosophy is to "reduce to practice" early in the development in order to fully understand the identified risks and flush out unknowns. Therefore, once the bench top testing had yielded some



In 2006, PADT was approached by a physician who had developed intellectual property that centered on endoscopic treatments for obesity and was founding a new company called SafeStitch Medical. PADT served as SafeStitch' engineering team for several years, developed a suite of related products, helped them achieve 510-k status on their first product, and supported their effort to build a permanent engineering organization. In June of 2010, SafeStitch raised \$5 Million of capital to help commercialize their technologies.

### DISCIPLINES EMPLOYED

- Mechanical Engineering
- Verification Testing
- Low Volume Manufacturing
- Support Animal Testing
- FDA 510-k Submission

promising concepts, we initiated a series of design-to-build test cycles to evaluate design alternatives in a simulated surgical environment.

This development effort led to the development of a suite of related products including endoscopes, dilators, bite blocks, suture knotters, etc. SafeStitch was successful in raising additional capital and started the process of becoming a full OEM. This included building an internal engineering team – which PADT supported. In June of 2010, SafeStitch raised \$5 Million of capital to continue developing new products and commercializing their technologies.

## PROJECT HIGHLIGHTS

Started with Safestitch' initial patent to develop early models of endoscopic system

Bench testing to develop and prove out the high-risk components

Proof-of-concept fabrication and testing in animal models. Testing started with pigs and progressed to Baboons

Development of complementary components including an airway biteblock and a suture knotter

Support during animal testing with prototypes

## TESTIMONIAL

*"For the last 3 years I have worked with PADT Medical as a physician-inventor of medical devices. Their engineering team is professional, punctual, and responsible. Their management is exemplary. I recommend PADT Medical to any potential Client."*

Charles J. Filipi M.D.  
Medical Director

SafeStitch Medical, Inc.

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