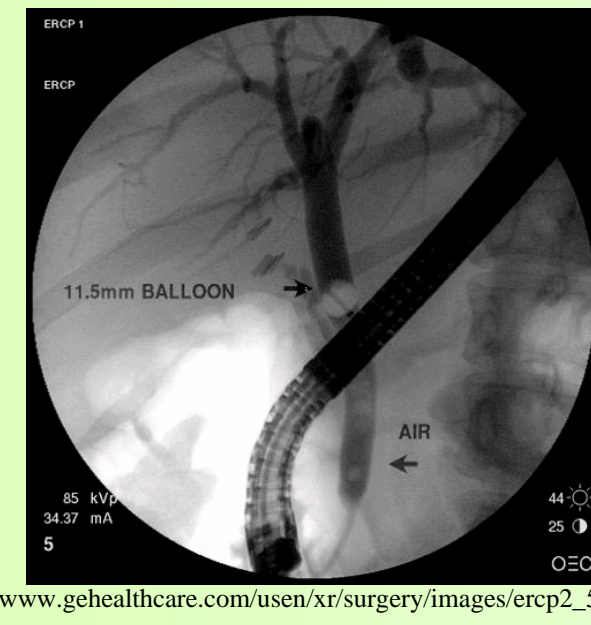


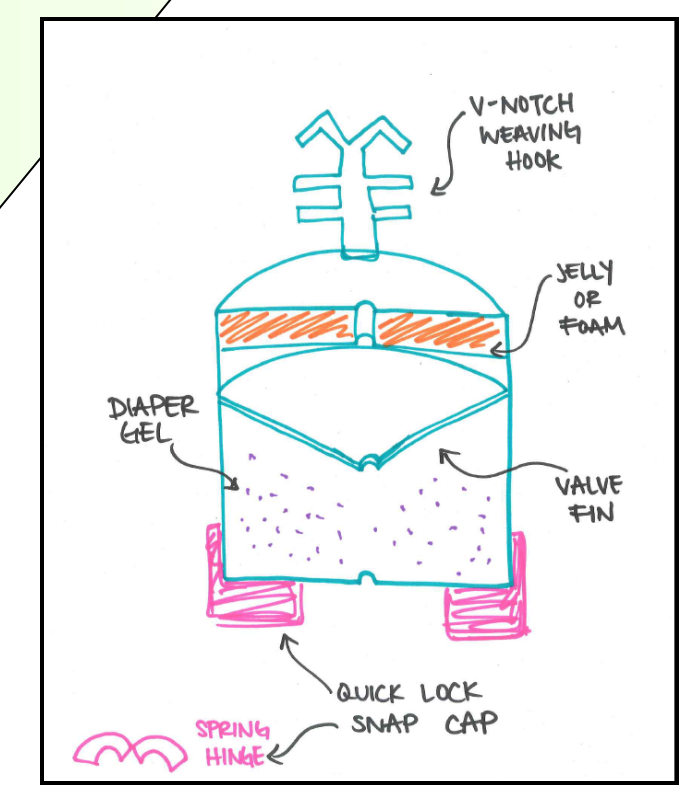
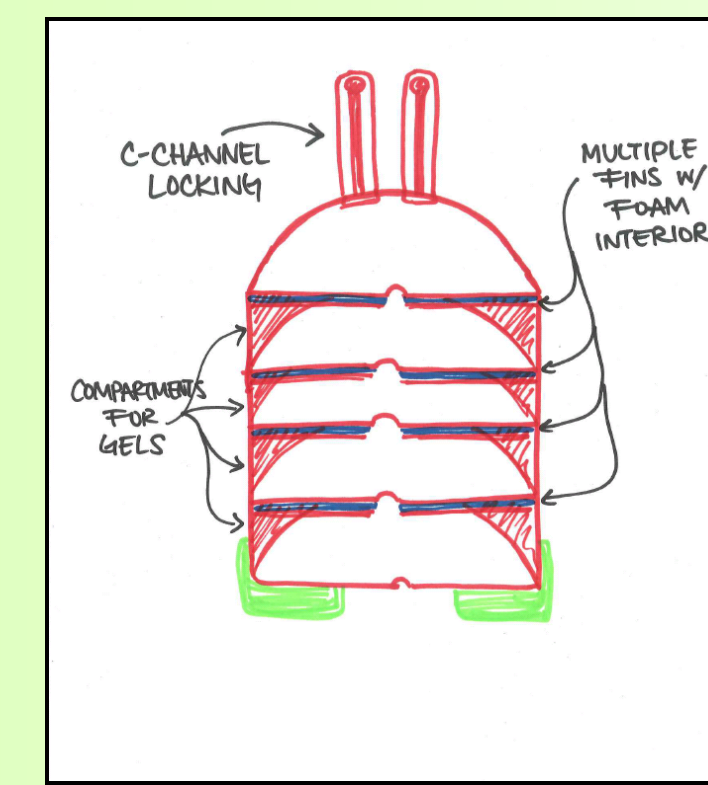
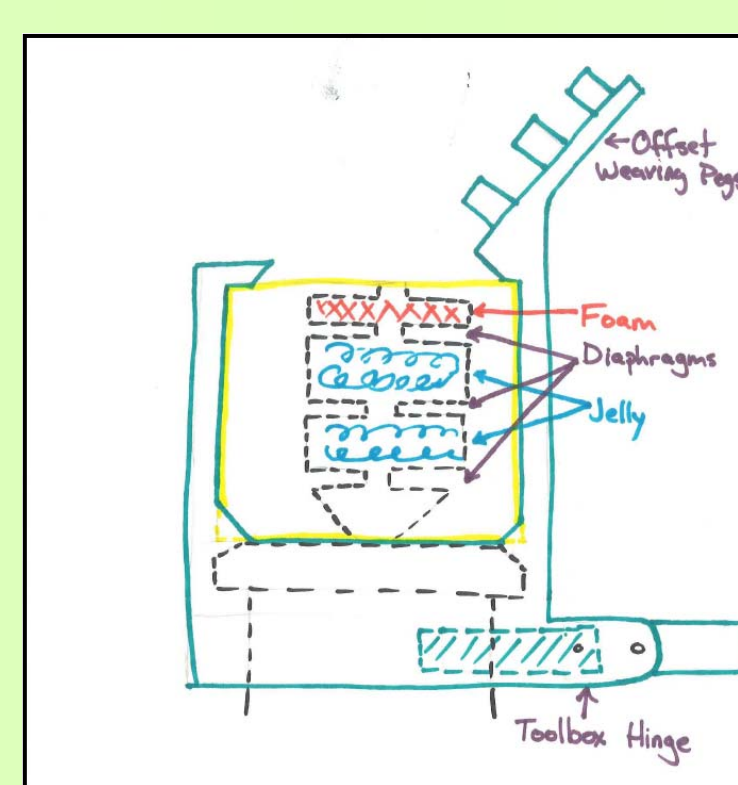
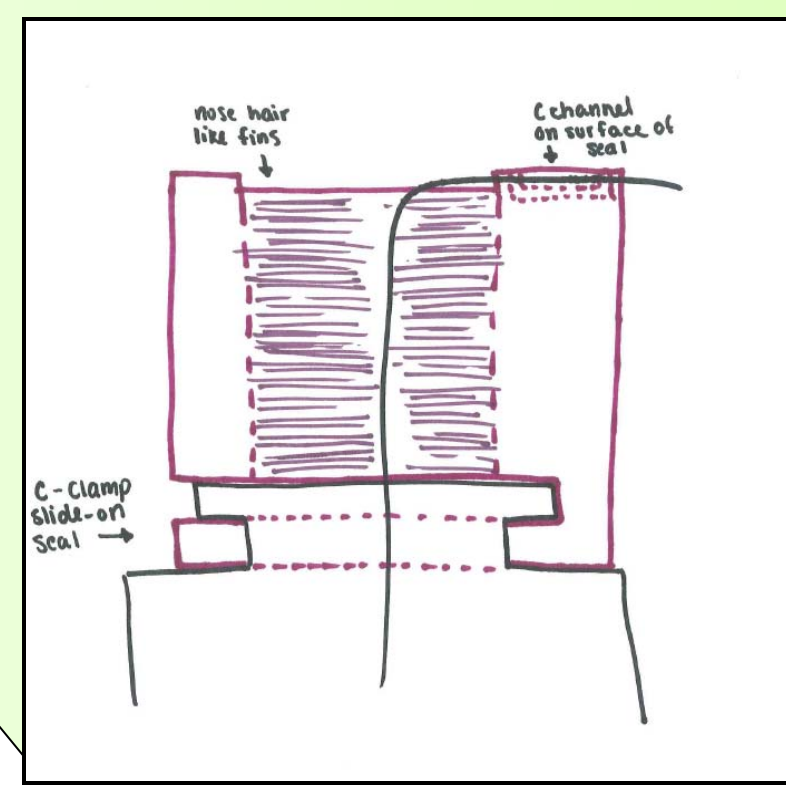
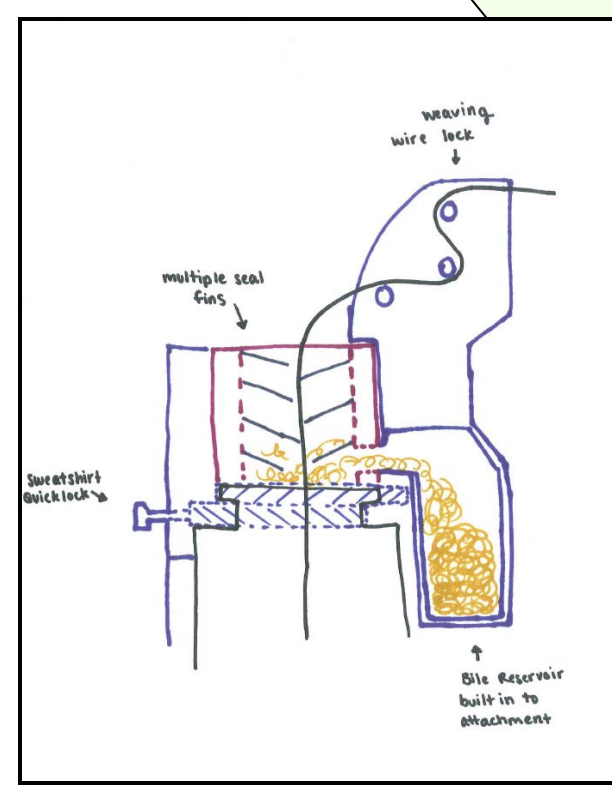
**Background Research**



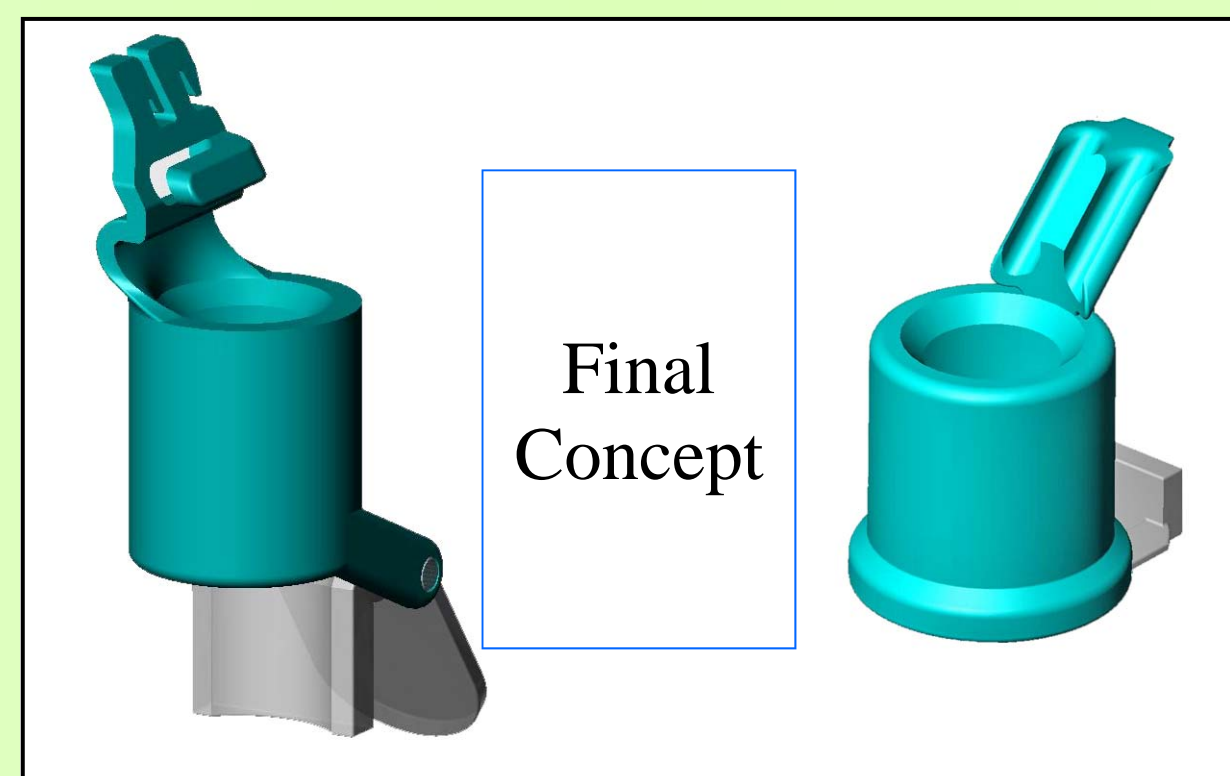
**Blue Sky Idea Generation**



**ILD Concepts**

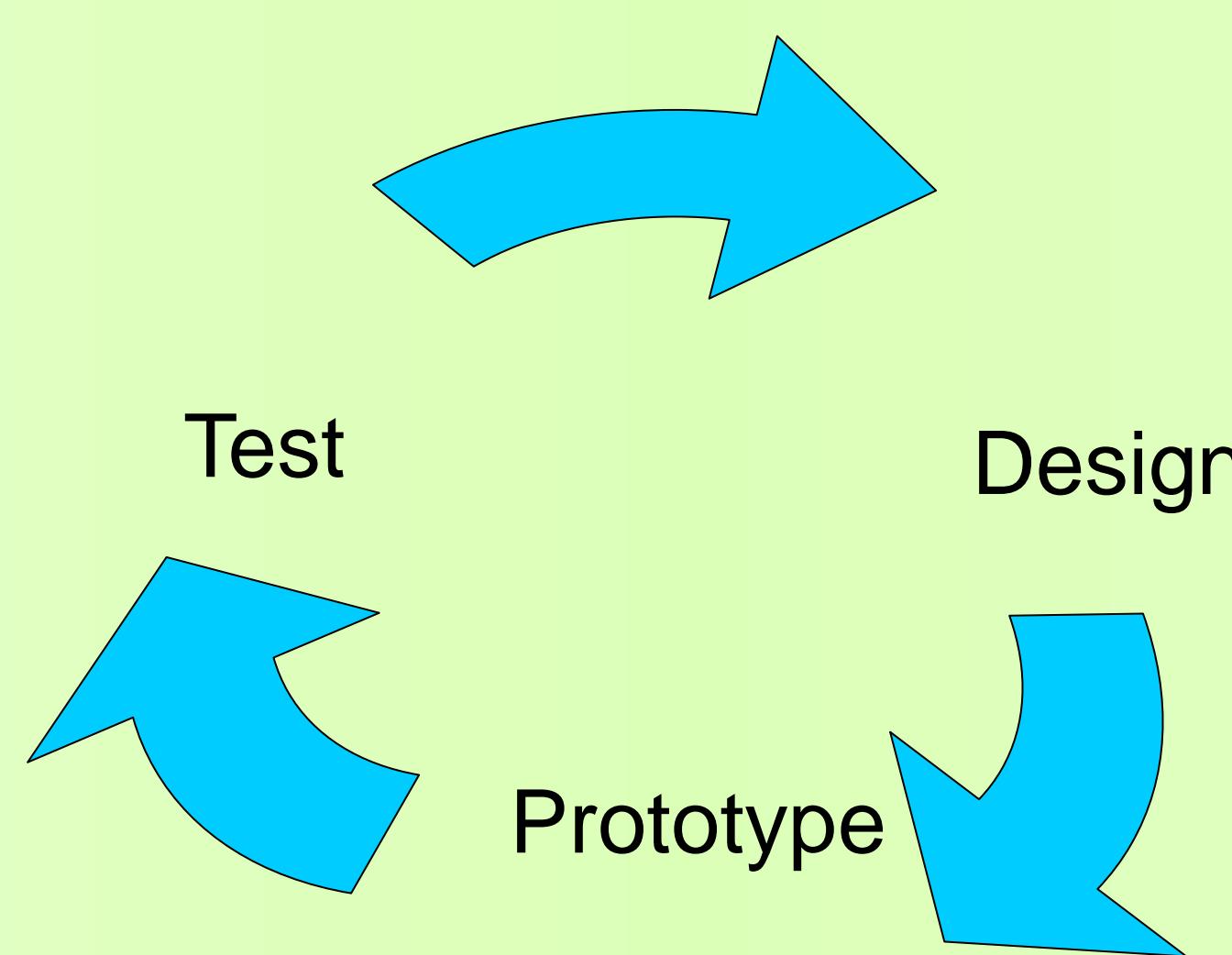
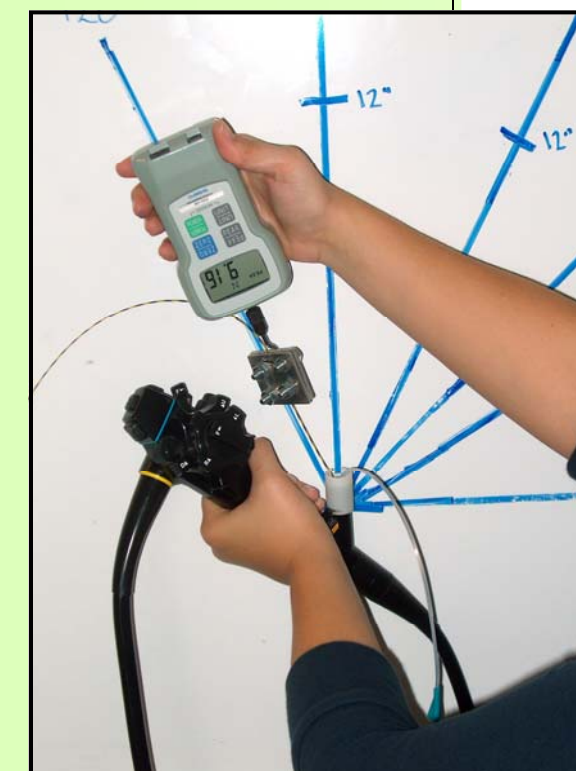
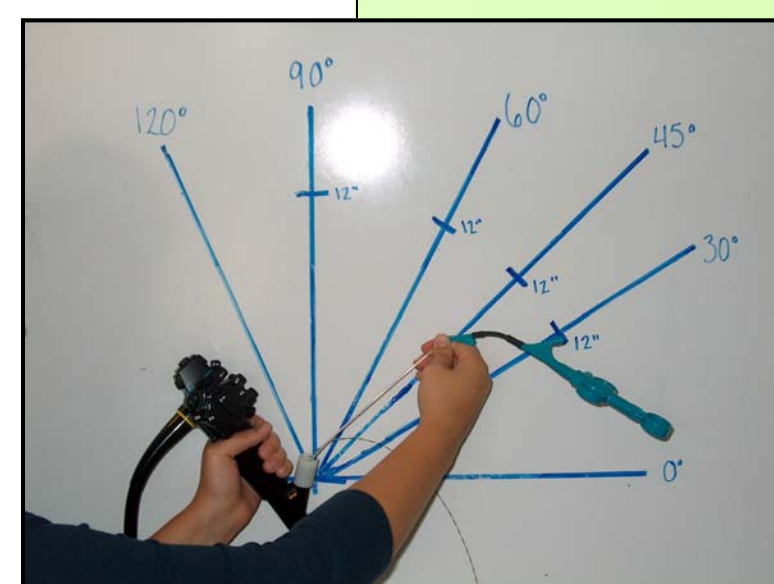


**Final 3**



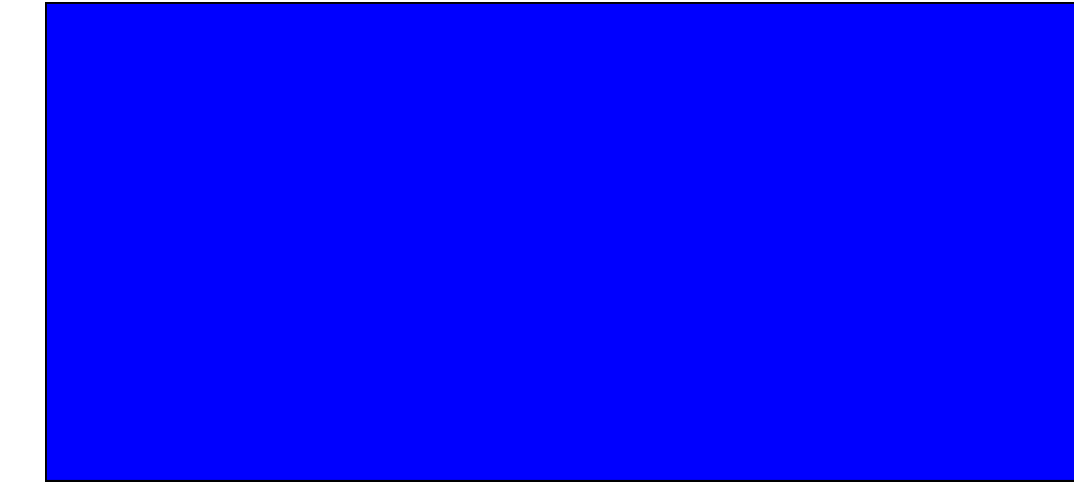
Final concept not shown for confidentiality reasons

**Testing**



**Final Prototype**





## Statement of Work

The 2006-2007 Boston Scientific Sealing team worked to develop an Integrated Locking Device (ILD) to be used with the Boston Scientific Rapid Exchange (RX) Biliary System. This project is a continuation of work performed by a previous SCOPE team in the spring of 2006. The current SCOPE team has designed, tested and prototyped one functional ILD. The final ILD was developed from the team's design constraints for the three main components of the ILD: endoscope attachment, wire locking, and sealing.



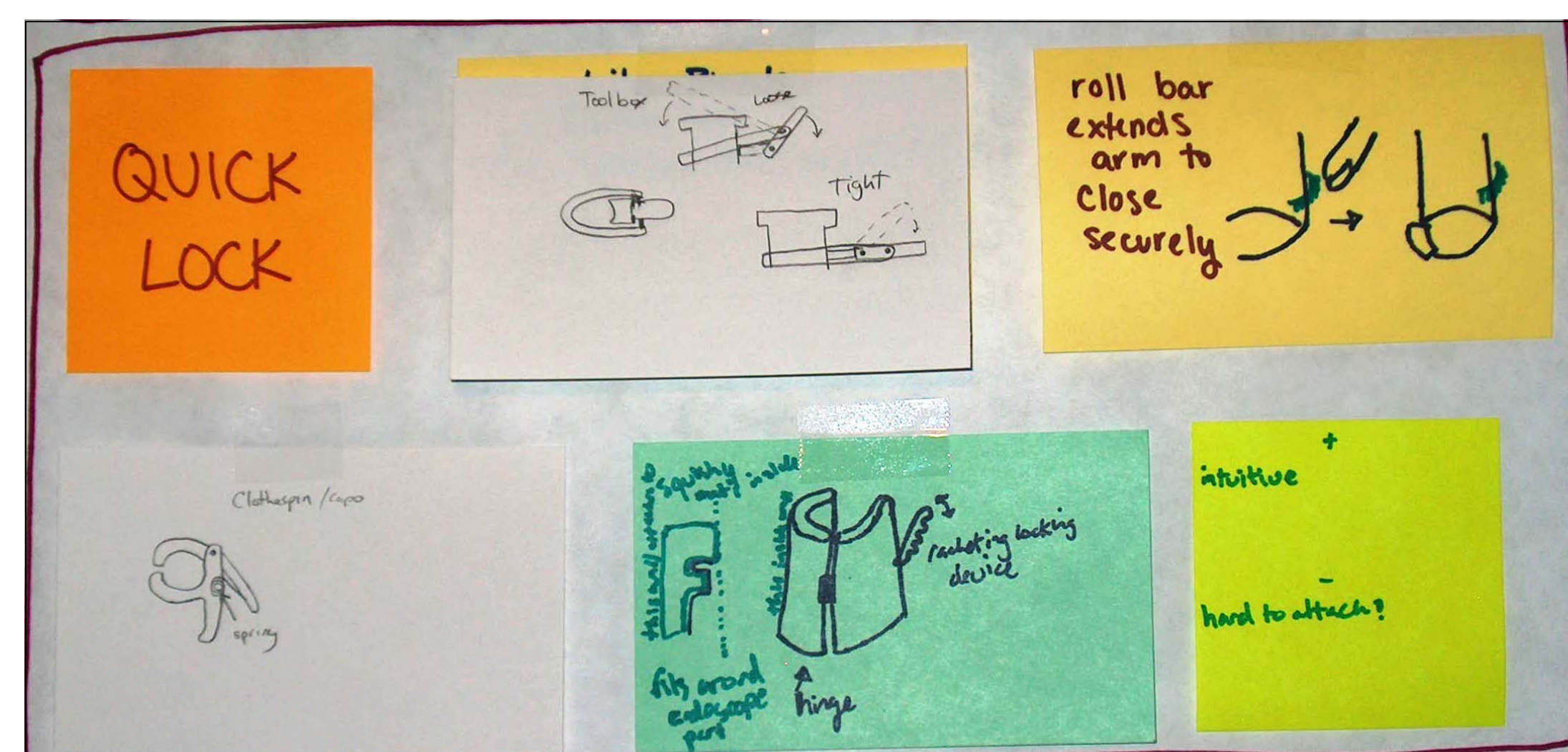
Current Boston Scientific device (left) and competitor Cook device (right)

## ERCP and Background Research

The team's integrated locking device (ILD) was designed for use with Endoscopic Retrograde Cholangiopancreatography (ERCP). ERCP is a procedure in which an endoscope passed into the body is used to diagnose and treat problems with the gastrointestinal tract. Once inside the body, various catheters are passed through the working channel of the endoscope. Air and bodily fluids also escape through the endoscope's working channel. To gain an appreciation for the demands of the product, team members attended ERCP procedures, an endoscopy conference, and conducted user interviews.

## Blue Sky Idea Generation

The team used information from procedure observations and user interviews to develop a set of design constraints; the design constraints outlined the characteristics of an ideal device. The team also brainstormed to generate a diversity of ideas. Ideas were then grouped by theme, as shown below. The ideas produced in the first round of brainstorming were purely conceptual.

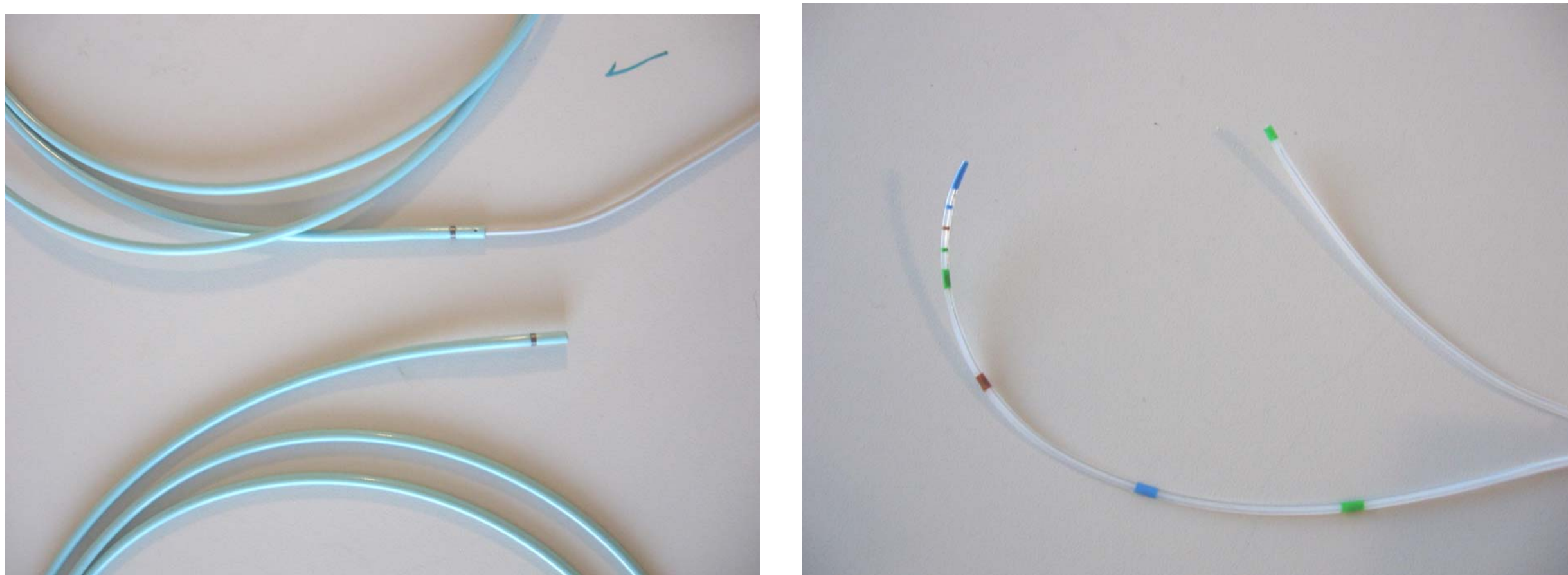


Grouping of ideas

## Idea Narrowing

From the brainstorming process, the team produced three preferred attaching and locking concepts. Sealing concepts were also narrowed and rough proof of concept prototypes were made. Concepts were chosen for their ability to meet design constraints and manufacturability. Through this process the team explored several decision making techniques. The team then used SLA to prototype attaching and locking mechanisms. These designs were modified with feedback from user interactions.

The team then narrowed to one concept locking and one attaching concept to begin the optimization process. The final concept was chosen on design constraints and user feedback. The seal design became a process of improvement of the current seal rather than a complete redesign.



## Testing and Optimization

The final attaching and locking concepts entered a cycle of testing and optimization. SLA prototypes and test setups were constructed to test specific functional areas outlined in the design constraints. The force required to attach the ILD was optimized using force gauges as was the force required for the wire to slip. Two usability studies were conducted at Boston Scientific, and the team also received feedback on the design to a practicing endosurgeon. After testing, the designs were refined and prototyped again.

To improve sealing, the team determined the failure mechanisms of the current seal. Failure modes were identified by measuring the time for a set pressure drop to occur and constructing a system diagram of the seal. The team modeled the current seal to optimize modifications. The modifications were made to the current design to improve functionality.



Test stand and catheters used for seal testing

## Final Products

The team's final product is a functional ILD with improved usability and recommendations for further development of the device.

On May 1, 2007, the team submitted to Boston Scientific a complete ILD as well as a report detailing the optimization process and further recommendations.