Improving Endoscopic Retrograde Cholangiopancreatography

Endoscopy

What is Endoscopy?
Endoscopy is a procedure that allows physician examination, diagnosis, and treatment of organs, joints, and cavities with the use of an endoscope.

Endoscope: a flexible device that employs a fiber optic and lens system to provide illumination and visualization for interior investigation of the body, through natural orifices.

Capabilities: suction irrigation tissue removal and sampling

ERCP

What is ERCP?
Endoscopic retrograde cholangiopancreatography or ERCP is an endoscopic procedure that uses a variety of tools to examine and treat disorders of the biliary tree, gallbladder, or pancreatic duct.

Most often, ERCP is used to detect gallstones, duct obstructions, and disease, such as cancer of the bile ducts, pancreatic cysts and tumors, biliary cirrhosis, and chronic pancreatitis.

Capabilities: biopsy visualization gallstone removal stent placement

Project Statement: Improve gaining and maintaining access to the biliary duct during ERCP

Surgery Visits
Physicians' interactions with Boston Scientific's current tools, and the difficulties they encounter were critical in shaping our understanding of how to improve the procedure

Problem Identification

Patient Anatomy:
- Peristalsis creates a moving target
- All ampullas are different
- Length of bile duct is variable

Post Ampulla Cannulation:
- Doctor doesn’t control the cannulating device
- Ampulla swells if irritated
- The ampulla is small, difficult to find, and constantly moving

Tool Mobility:
- Movements required to maneuver endoscope are not intuitive
- Aligning the guidewire/sphincterotome for cannulation is difficult
- No 1:1 rotation
- Sphincterotome gets jammed with guidewire in scope

Visualization Issues:
- 3D environment is viewed in 2D
- Cant visualize what’s behind the ampulla

Our Goal:
Create a new generation of device that builds upon Boston Scientific’s physician controlled line of products.

Existing Technology:

Boston Scientific Hydratome
Features: Cutting wire, rapid exchange system, dye injection
Use: Used in most ERCP procedures cannulations and sphincterotomy The Market: Tool widely accepted for ERCP procedures

Spyscope
Features: 6000 pixel fiber optic channel, vacuum and irrigation lines, and a tool channel
Use: To visualize inside the biliary duct when standard procedures fail to Market: Released mid-2007, currently used only when regular sphincterotome is insufficient

Conmed Axcess
Features: Steerable tip, cutting wire, dye injection
Use: Used for ERCP procedures and sphincterotomies requiring additional tip motion for cannulation purposes
Market: Recently released, little market penetration

The Team:
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Boston Scientific is the world’s largest medical device company dedicated to less-invasive medicine. Boston Scientific’s mission is to improve the quality of patient care and the productivity of health care delivery through the development and advocacy of less-invasive medical devices and procedures.