

Improving Endoscopic Retrograde Cholangiopancreatography



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.

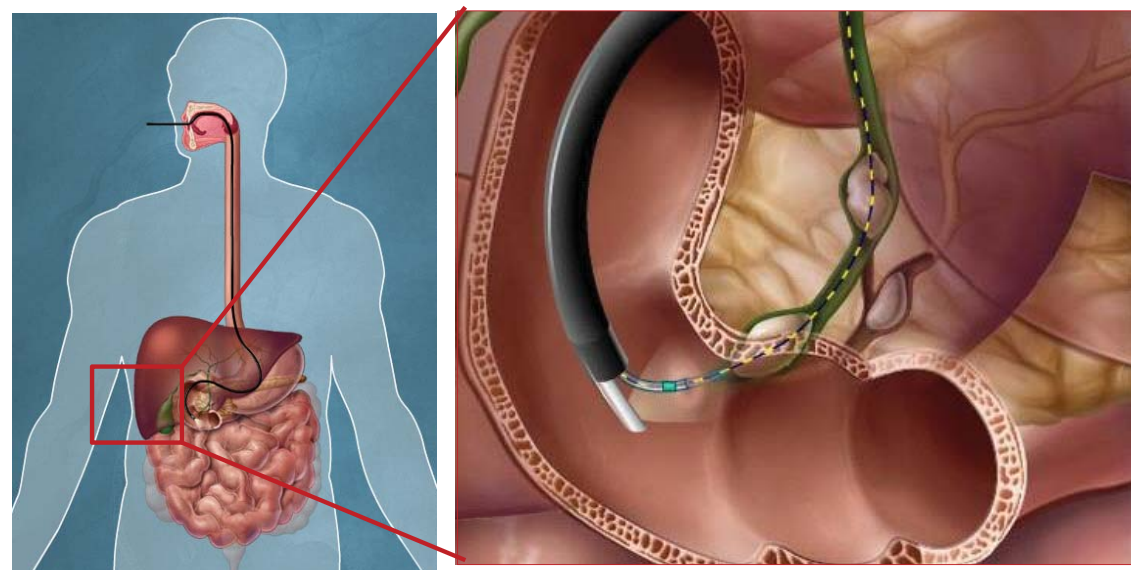
Endoscopy

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 administration of drugs
tissue removal and sampling



Removal of gallstones during ERCP

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.

What does ERCP treat?

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



Fluoroscopic (x-ray) view of ERCP



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



Beth Israel Deaconess Medical Center Rhode Island Hospital
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Problem Identification

Patient Anatomy:

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

Ampulla Cannulation:

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

Post Ampulla Cannulation:

- Selectively cannulating the bile duct is difficult
- Touching the pancreas is easy
- Ducts are not always open
- Tools can get stuck

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

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 Axxess

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



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