# SpyGlass™ DS

## Direct Visualization System

Boston Scientific
Advancing science for life™


*You're going to want to see this™*

## Media Kit

# Your Work with the SpyGlass DS System is News

Your hospital is a leader in diagnosing and treating pancreatico-biliary disease and has adopted the latest industry advancement in cholangioscopy. Your physicians are improving patient care, using innovative technology such as the **SpyGlass DS Direct Visualization System** to help **diagnose** and **treat diseases** of the **pancreatico-biliary system**, including pancreatic cancer.

Please take a moment to review the content within this media kit, which was specifically designed to help you publicize your hospital's successful use of this leading technology.

## ERCP Stats

- More than **500,000** Americans undergo **ERCP** procedures each year
- Data shows that up to **70%** of ERCPs using conventional brush cytology for tissue diagnosis are **inconclusive**, requiring additional testing or repeat procedures
- According to the Lustgarten Foundation, pancreatic cancer is the 4th leading cause of cancer death in the US, with only a **6%** five-year survival rate.

## Clinical Benefits of the SpyGlass DS System

- May **reduce** the need for additional **testing and repeat procedures**
- May **alter diagnosis or treatment** strategies for patients previously examined with ERCP
- Approximately **doubles biopsy sensitivity** compared to brush cytology*

*Yang Chen, MD, et al, *GIE*, Vol. 74, 2011

# Contact Us

Please contact us at **SpyDSPR@bsci.com** with:

- Questions about the SpyGlass DS System or Boston Scientific
- Requests for additional information
- PR partnership opportunities

**Share Your Feedback**

**We want to hear from you!**
Please take a few minutes to complete this short survey and provide your feedback about this media kit.

# Share Your Patient Stories

Boston Scientific may be able to partner with your institution to help you communicate and promote successful patient outcomes using this technology. Please contact us at **SpyDSPR@bsci.com**.


# SpyGlass **DS** System

## Digital + Simple = DS

Launched in 2015, the SpyGlass DS System enables **high resolution imaging** and **therapy** during an ERCP procedure to target biopsies and fragment stones, which may result in more efficient evaluation and help **reduce the need** for additional testing and **repeat procedures** compared to traditional ERCP, and enable patients to receive treatment sooner.

- 510(k) cleared for cholangioscopy and pancreatoscopy procedures
- Built on the ground-breaking technology of the original SpyGlass System

*You're going to want to see this™*

Learn more about an ERCP procedure

Learn more about the importance of direct visualization

SpyGlass DS Scope Catheter Tip with SpyBite™ Forceps for Tissue Acquisition

SpyGlass DS Scope Catheter Tip with EHL for Stone Management

SpyGlass DS Scope Catheter Tip with Laser for Stone Management

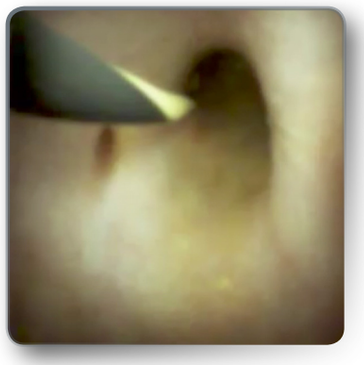
# SpyGlass DS System

## Digital

- Improved image quality with **four times higher resolution** and a **60% wider field of view***
- Fully integrated SpyScope™ DS Access and Delivery catheter **(single-use scope)** eliminates probe reprocessing and image degradation over multiple uses

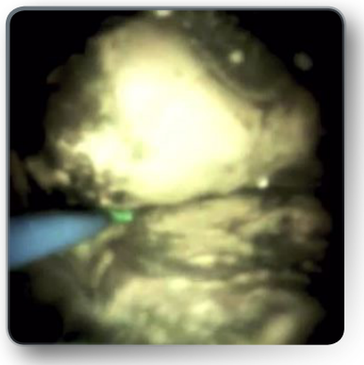
## Simple

- Designed to optimize procedural efficiency and productivity
- Features an integrated controller that fits on a standard ERCP cart for **improved accessibility** and **'plug and play' setup**
- **Features improved set-up to help reduce procedure time**
- Can be performed as **an extension of any ERCP procedure**, potentially reducing the need for **additional testing** and **repeat procedures** compared to traditional ERCP



View of a normal bile duct

Biopsy in the bile duct using SpyBite™ Forceps



Fragmenting a large stone using the laser


SpyGlass DS Digital Controller fits on a standard ERCP cart

*Compared to first generation SpyGlass System

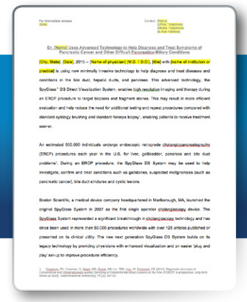
# SpyGlass DS System

## Media Outreach Tools

(An internet connection is needed to access these tools)


Animation

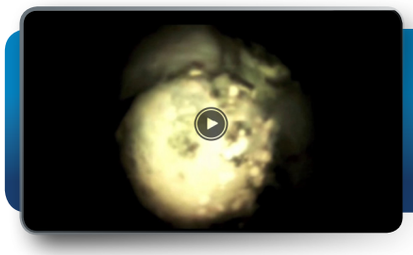
Procedural Images



Template Press Release

Product Photography

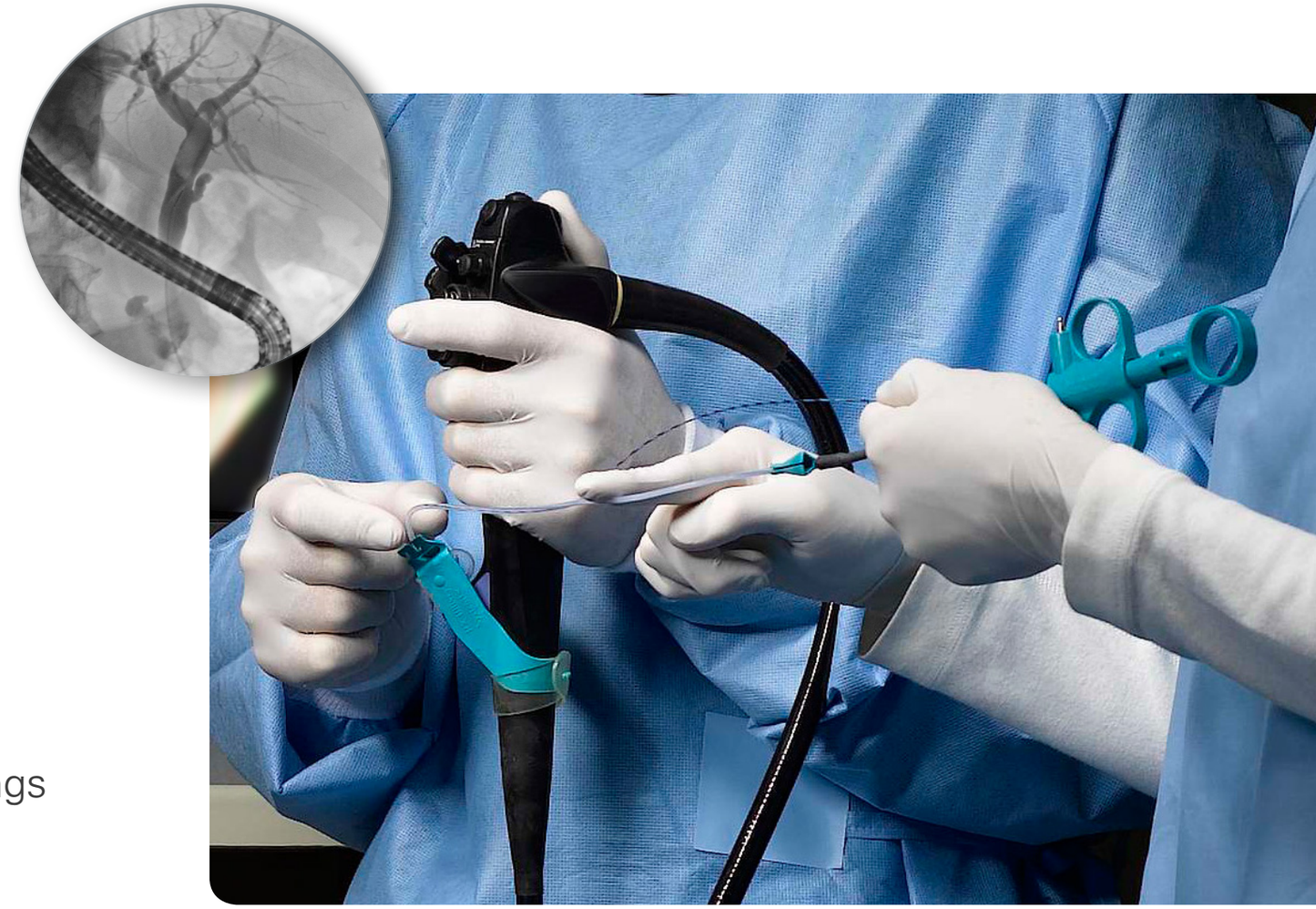

Boston Scientific Multimedia Press Release



Broll Procedural Video Footage

# What is ERCP?

- Stands for Endoscopic Retrograde Cholangiopancreatography
- Procedure used to evaluate and diagnose conditions in the bile duct, pancreas, and liver, such as:
  - gallstones
  - suspected malignancies
  - bile duct strictures
  - cystic lesions
- Radiographic images (similar to black and white x-rays) are taken to document findings
- More than **500,000 people** in the US undergo **ERCP procedures** each year



# What is Cholangiopancreatoscopy?

If x-ray imaging is not sufficient to make a definitive diagnosis or therapeutic intervention requires **direct visualization**, the physician may perform cholangioscopy or pancreatoscopy.

- Cholangioscopy is the examination of the bile ducts using an endoscope to enable direct visualization of the biliary tree during ERCP.
- Direct visualization of the bile and pancreatic ducts during ERCP can help obtain biopsy specimens, lead to the diagnosis of abnormalities, and guide stone therapy.
- Prior to the launch of the SpyGlass System, cholangioscopy was not widely used because early cholangioscopies required two operators, were very fragile, and had many technical limitations.

First Introduced in 1976


Cholangioscopy Today

# SpyGlass System

Launched in 2007, the first generation SpyGlass System helped re-establish cholangioscopy and pancreatoscopy as a valuable **diagnostic and therapeutic procedure** by allowing a **single operator** to perform the procedures as well as guide devices to examine, diagnose and treat conditions such as gallstones and suspected malignancies of the biliary tree and pancreas.

- Performed in more than **50,000 patient procedures**
- Published clinical data in more than **150 abstracts and articles in medical journals**

## Clinical Registry Results*

- Stone removal success reported in **92% of patients**
- Clinical management was altered in **64% of patients** undergoing diagnostic procedures during ERCP using cholangioscopy with the SpyGlass System.

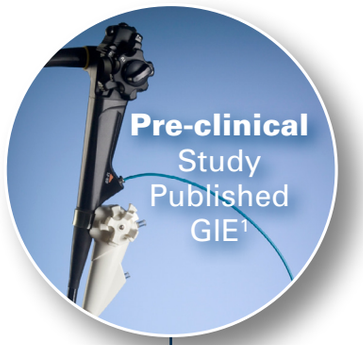
* 297 patients, 15 centers. Yang Chen, MD, et al, *GIE*, Vol. 74, 2011

# History of Cholangioscopy

**1970s**

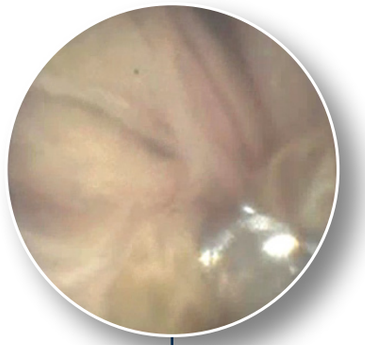
**1st** Documented use of ‘mother-baby’ cholangioscope

**Slow Adoption**
Due to technical and cost limitations




**2007**

SpyGlass System Launched



**2009**

**510(k)** Pancreatoscopy Indication

**25,000** cases
**60+** publications
**600** systems

**2011**

Clinical Registry in GIE - **297** patients - largest study of peroral Cholangioscopy[2]

**50,000** cases
**150+** publications
**1,000** systems

**2014**

AMEA* clinical registry: Targeting **25** sites, **500** patients, **12** countries


**2015**

**510(k)** clearance of next generation SpyGlass DS Direct Visualization System

1.Preclinical characteristics of the SpyGlass peroral cholangioscopy system for direct access, visualization and biopsy, Yang Chen, MD. GIE, Vol. 65, No. 2: 2007.
2.Single-operator Cholangioscopy in patients requiring evaluation of bile duct disease or therapy of biliary stones (with videos), Yang Chen et al. GIE, Vol 74, Issue 4, October 2011.
* Asia, Middle East and Africa


# About Boston Scientific

- Leading innovator of medical solutions that improve the health of patients around the world.
- Dedicated to transforming patient lives by developing diagnostic and therapeutic devices that support less invasive, more efficient procedures for a variety of conditions.
- Advancing important clinical research, supporting education programs, and helping healthcare institutions deliver high quality healthcare while managing costs.

› www.bostonscientific.com

## Boston Scientific Endoscopy Quick Facts

**Over 1500**
technologies designed to support the effective and efficient treatment of GI and Pulmonary diseases

**Over 100**
Medical diseases and conditions are addressed by our less invasive technologies

**Over 20 million**
patients a year could benefit from our less invasive treatment options

**27 patients per minute or 1 patient every 2 seconds**
impacted by our technologies

Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device.

**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.

Boston Scientific

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