SpyGlass™ DS II Direct Visualization System

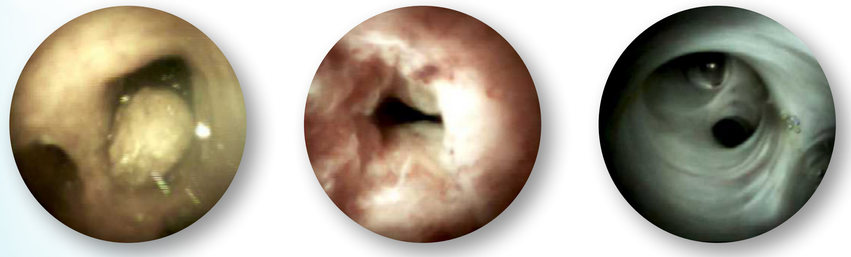
Boston Scientific
Advancing science for life™

The SpyGlass DS System

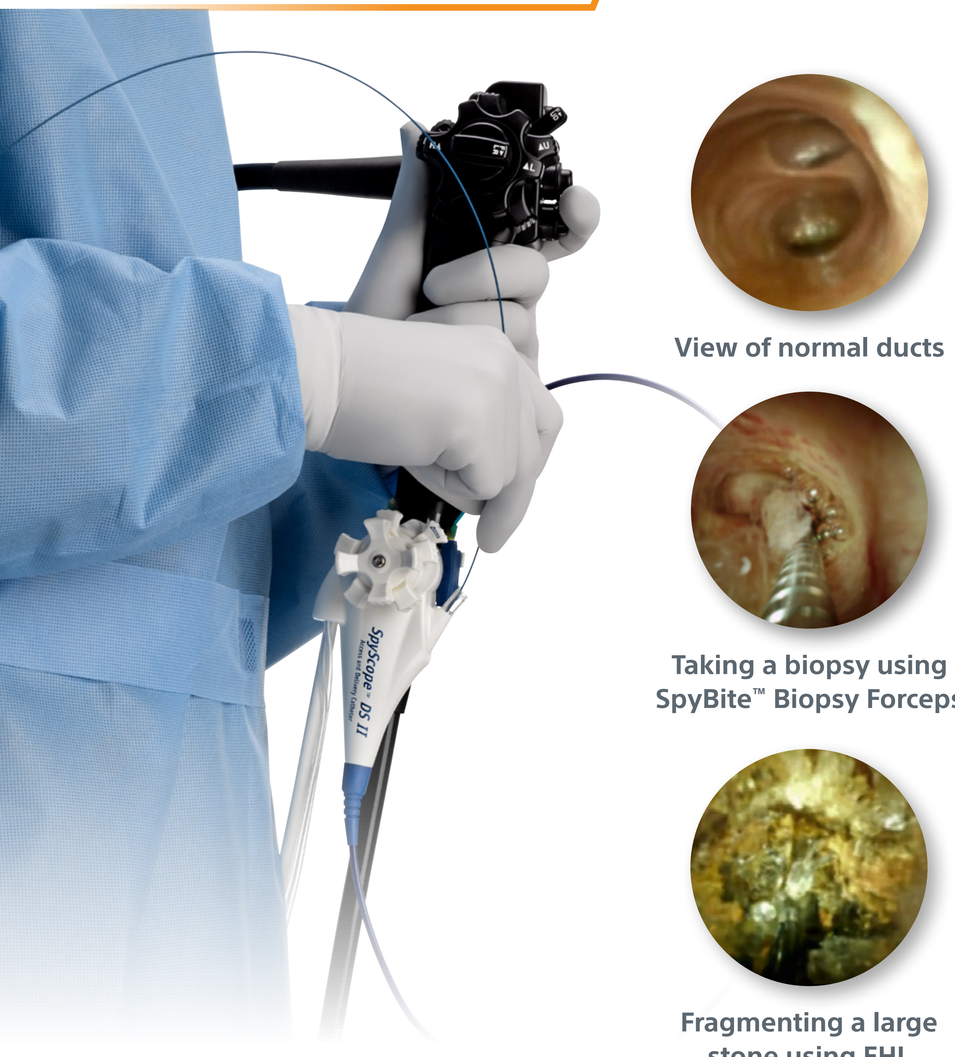
A Full Suite of Solutions

Ordering Information

Additional Resources



WHETHER CASES ARE SIMPLE OR COMPLEX,
THE STANDARD OF CARE SHOULD BE ANYTHING BUT STANDARD.



View of normal ducts

Taking a biopsy using SpyBite™ Biopsy Forceps

Fragmenting a large stone using EHL

The SpyGlass™ DS System

The SpyGlass DS System enables high resolution imaging and therapy during an endoscopic retrograde cholangiopancreatography (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**[6]. The system enables direct visualization of the bile and pancreatic ducts and can help obtain biopsy specimens, lead to the diagnosis of abnormalities, and guide stone therapy.

Since its launch in 2015, the SpyGlass DS System has impacted more than **80,000 patient lives** in more than **65 countries**.

80,000
PATIENTS

65
COUNTRIES

Learn More About the SpyGlass DS System

About Cholangioscopy

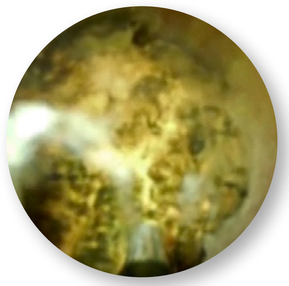
The SpyGlass™ DS System provides **important clinical**, **operational and economic benefits for managing patients** with complex pancreaticobiliary disorders, such as difficult stones and indeterminate strictures.

85%
ALTERED

In a clinical study of 289 patients, **clinical management was altered in 85% of patients** undergoing diagnostic ERCP with cholangioscopy.[1,2]

95%
SUCCESS

95% stone clearance rates[2] may reduce the need for more invasive and costly procedures, which may have a significant impact on patient outcomes and patient satisfaction.

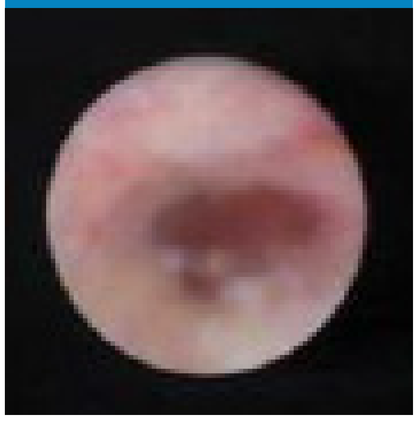
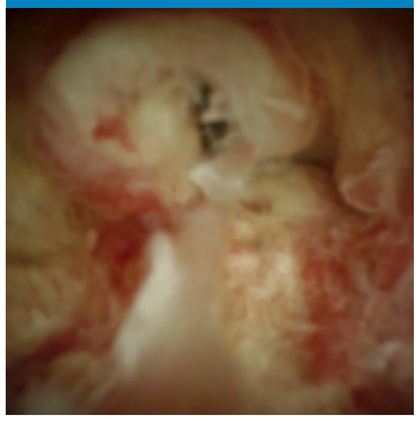


May enable **faster, more definitive cancer diagnosis** by allowing clinicians to obtain biopsies of tissue under direct visualization, improving sensitivity and diagnostic yield.[1*]

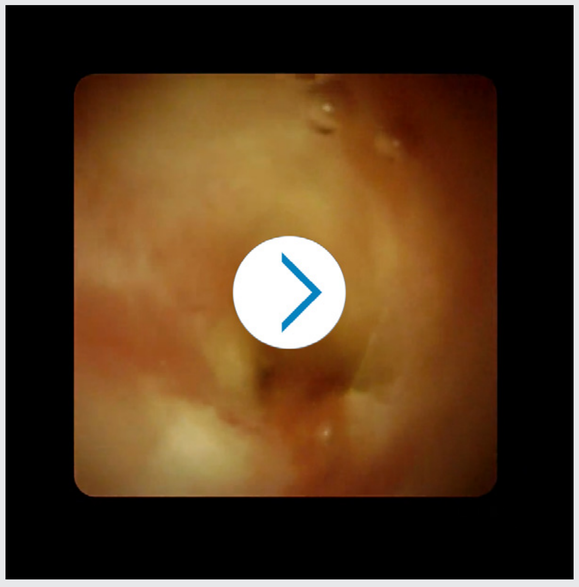
A recent study showed the SpyGlass DS System provided enhanced diagnostic yield, shorter procedure times, and less radiation exposure compared to a fiberoptic single-operator cholangiopancreatoscopy system.[10]

Fluoroscopy vs Digital Imaging

Does reliance upon two dimensional, black and white imaging (fluoroscopy) enable the most effective way to diagnose and treat pancreaticobiliary strictures and stones?

Fluoroscopic Cytology Brush	First Generation SpyGlass™ System	SpyGlass DS System	SpyGlass DS II System
			
SENSITIVITY 30%[1,3,4,5,6]	SENSITIVITY 49%[7]	SENSITIVITY 86%[8]	

Click to watch video below



View of Cholangiocarcinoma
Video provided courtesy of
Isaac Raijman, M.D.

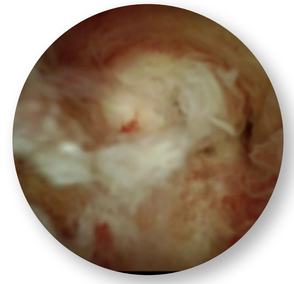
SpyScope™ DS II Access & Delivery Catheter

Our Purpose is Clear:

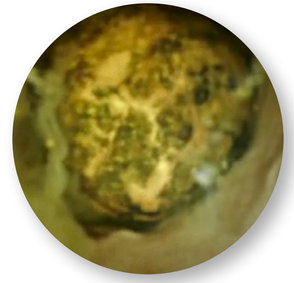
The 3rd Generation SpyScope DS II Access & Delivery Catheter

Built on the **ground-breaking technology** of the SpyScope DS Catheter, the SpyScope DS II Catheter features **increased resolution** and **adjusted lighting** to provide physicians with an **even better view** of the biliary and pancreatic ducts.

View of Biliary Duct



View of Cholangiocarcinoma



View of Biliary Stone

SpyScope DS II Catheter

New CMOS chip featuring increased resolution

Adjusted lighting designed to reduce light flare, improve lighting in the corners of the video, and provide an enhanced view down the lumen

Increased resolution, at 2.5x that of the SpyScope DS Catheter**

- HDR processing for improved visibility
- Easy platform upgrade process

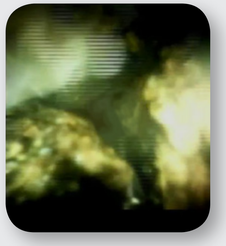
2.5x INCREASED RESOLUTION

An Expanding Suite of Compatible Accessory Devices

SpyGlass™ Retrieval Basket

The new SpyGlass Retrieval Basket can be used to capture and remove residual biliary and pancreatic stones and stone fragments visualized with the SpyGlass DS System.

Stone Management

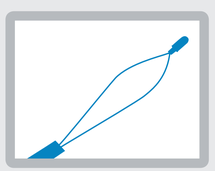


Direct visualization stone clearance using EHL has been shown to be clinically effective with demonstrated **procedural success**, with single-session stone clearance rates of ~75%[2].

In a recent study, **15/50 patients (30%) were found to have residual biliary stones** that were not seen with occlusion cholangiogram, but were detected using the SpyGlass DS System.[11]

Achieving single session stone clearance and reducing the need for a repeat procedure(s) may deliver greater patient satisfaction and decrease unnecessary procedural costs.

SpyGlass Retrieval Snare



The new SpyGlass Retrieval Snare **is designed to enable efficient capture and removal of foreign bodies** in the biliary and pancreatic ducts, such as migrated plastic stents, during an ERCP procedure.

Capture and removal of a biliary plastic stent using the SpyGlass Retrieval Snare.

A History of Innovation in Cholangioscopy

1970
First documented use of 'mother-baby' cholangioscopy

2007
Launch of the First Generation SpyGlass™ System and SpyBite™ Biopsy Forceps

2011
Publication of Clinical Registry in GIE 297 patients – largest study at the time of peroral cholangioscopy[7]

2015
Winner – R&D 100 Award

2015
Launch of the Next Generation SpyGlass DS System

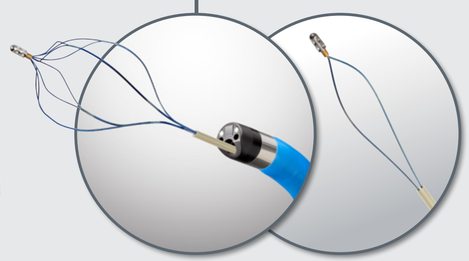
2016
Winner – Silver MEDA Award in the Radiological and Electromechanical Devices category

2017
Co-exclusive distribution with Northgate Technologies, enabling access of EHL globally

2018
Launch of the 3rd generation SpyScope™ DSII Catheter, SpyGlass Retrieval Basket and SpyGlass Retreival snare.

1970 2007 2011 2015 2016 2017 2018 *Continuing Innovation*

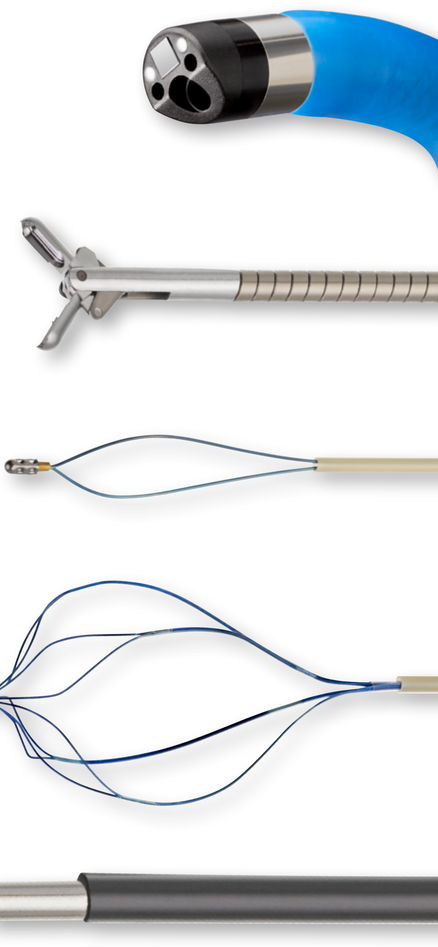
Slow adoption due to technical & cost limitations.



For the latest cholangiosopy news and updates, visit www.bostonscientific.com/cholangioscopy

Ordering Information

Order Number	Product Description
SpyGlass™ DS System Capital	
M00546650	SpyGlass™ DS Digital Controller
SpyGlass DS System Device	
M00546610	SpyScope™ DS II Access & Delivery Catheter
M00546600	SpyScope DS Access and Delivery Catheter



Order Number	Product Description	Cable Diameter (in / mm)	Jaw Outer Diameter (mm)	Jaw Opening (mm)	Working Length (cm)	Required Endoscope working Channel (mm)	Diameter (mm) (open)
SpyGlass DS Accessory Devices (Optional)							
M00546270	SpyBite™ Biopsy Forceps	0.039/1.0	1.0	4.1/55°	286	1.2	N/A
M00546550	SpyGlass Retrieval Basket	NA	NA	NA	286	1.2	15
M00546560	SpyGlass Retrieval Snare	NA	NA	NA	286	1.2	9

Order Number	Product Description
Biliary EHL Probe	
M00546620	1.9Fr., 375cm Biliary EHL Probe
Autolith™ Touch System	
M00546680	Autolith Touch EHL Generator

Order Number	Product Description
Autolith Touch System Accessories	
M00546750	Autolith Touch Extender Cable
M00546760	Autolith Touch Foot Pedal

Download the Product Catalog

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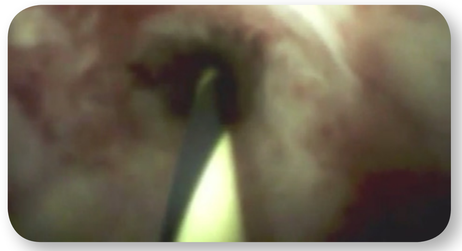
Additional Resources

LET'S GO!

Cholangioscopy and Pancreatoscopy Video Atlas

Explore our library of short video clips to help familiarize yourself with the appearance of various pancreatic and biliary findings as seen using cholangioscopy with the SpyGlass DS System. *(Internet Required)*



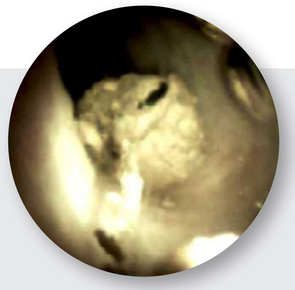
LET'S GO!

Cholangioscopy Image Reference Guide

Become familiar with the appearance of strictures, villous lesions, stone disease, and more using the SpyGlass DS System. *(Internet Required)*

Normal Duct

Cholangiocarcinoma



Cystic Duct Stone

LET'S GO!

Visit EndoSuite.com to watch presentations, programs and case studies featuring the SpyGlass™ DS System. *(Internet Required)*

Keep up to date with the latest resources and information by visiting www.bostonscientific.com/cholangioscopy

Follow us on Twitter

*Compared to cytology brushing.

**Because the analysis of sensitivity in intrinsic versus extrinsic disease was limited to patients with a final diagnosis of malignancy, no computation of specificity was possible.

References:

1. J Jailwala, E Fogel, S Sherman, et al. Triple-tissue sampling at ERCP in malignant biliary obstruction. Gastrointest Endosc 2000; 51(4):383-390.
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5. Ornellas LC et al. Comparison between endoscopic brush cytology performed before and after biliary stricture dilation for cancer detection. 2006 (41)1: 20-23.
6. Draganov et al., Diagnostic accuracy of conventional and cholangioscopy-guided sampling of indeterminate biliary lesions at thetime of ERCP: a prospective, long-term follow-up study, GIE, Vol. 75 (2); February 2012.
7. Chen Y et al, Single-operator cholangioscopy in patients requiring evaluation of bile duct disease or therapy of biliary stones (with videos). Gastrointest Endosc 2011; 74:805-814.
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10. Pleskow et al. "Apple Far from the Tree": comparative effectiveness of fiberoptic single-operator cholangiopancreatoscopy (FSOCP) and digital SOCP (DSOCP). HPB 2018, 20, 285–288.
11. Sejpal et al. Prospective Evaluation of Digital Peroral Cholangioscopy for the Detection of Residual Biliary Stones That Are Missed With Conventional ERCP: an Interim Analysis. GIE. May 2017Volume 85, Issue 5, Supplement, Page AB618.
12. Ramchandani, M. et al. Single Operator Cholangioscopy for the evaluation and diagnosis of Indeterminate biliary strictures -Results from a Large Multi-national Registry. DDW 2017.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. This material not intended for use in France.

Rx only.

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Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com/Gastro
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