

SpyGlass™ DS

Direct Visualisation System

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*You're going to
want to see this.™*



SpyGlass™ DS Direct Visualisation System

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



Fluoroscopy image of
Left Hepatic Duct (LHD) villous lesion



SpyGlass™ DS System image showing
LHD villous lesion in same patient

The SpyGlass DS System allows you to realise the benefits of cholangiopancreatography as an extension of the ERCP procedure and new standard of care[†].

The SpyGlass System Registry* of nearly 300 patients across 15 centers demonstrated:

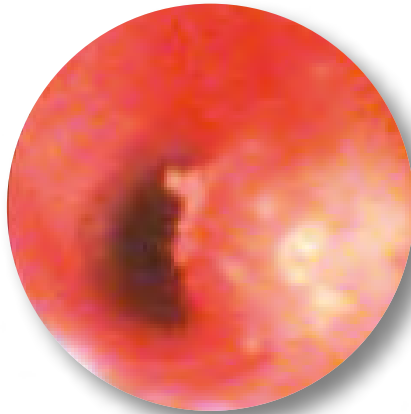
- Increased sensitivity vs standard ERCP with fluoroscopy-guided biopsy
- Altered clinical management (in 64% of the diagnostic procedures)
- High success rate for removing large or difficult stones (92%)

Digital + **Simple** = **DS**

Digital

Enhanced Visualisation*

- **Digital sensor** with ~4x resolution
- 60% **wider field of view**
- **Automatic** light control & LED illumination
- Dedicated **irrigation** and **aspiration** connections to clear field of view



First generation
SpyGlass™ System image



SpyGlass DS System image

Simple



Improved Usability*

- **Redesigned** working channel for passing accessories
- Dedicated **irrigation** and **aspiration** channels/connections
- Fixed imager for **consistent steering**
- **Single-use** digital scope



Simplified Set-up*

- **Set-up** time **under 5 minutes**
- Equipment designed to **fit on a standard endoscopy cart**
- Automatic white **balance** and **focus**
- **Integrated digital sensor** - NO fragile optical probe to load or reprocess

Accessories

SpyBite™ Biopsy Forceps

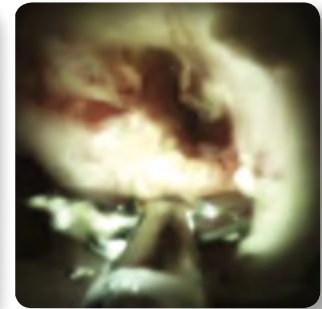
The SpyBite Biopsy Forceps are intended to be used with the SpyScope™ DS Access and Delivery Catheter to enable **targeted specimen sampling** under **direct visualisation** throughout the pancreaticobiliary system.

Sensitivity

Shown to be more than 1.6 times greater for targeted biopsies taken under direct visualisation compared to brushing or fluoro-guided biopsy alone.¹

Specifications

- 1mm outer diameter
- Biopsy cup: 4.1mm opening at 55°
- Central spike in specimen cup aids in securing samples in difficult anatomy

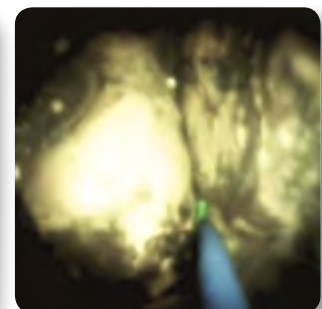
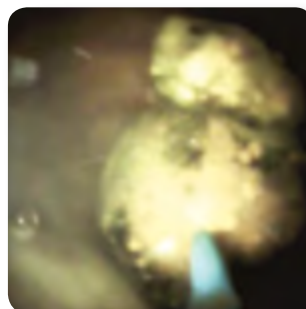


Taking biopsies under direct visualisation using miniature SpyBite Forceps

EHL and Holmium Laser

Both EHL and Holmium Laser may be used in conjunction with the SpyGlass™ DS System to manage large biliary stones.

Northgate Technologies, Inc. (EHL*) and Lumenis (Laser**) have demonstrated compatibility with this system.



Fragmenting a large biliary stone using a holmium laser probe with SpyGlass DS System

* Biliary EHL Probe, #9-202-3751, 1.9 Fr, 375cm

** SlimLine GITM Laser Probe, #0644-007-01, 1.8Fr

1. Diagnostic accuracy of conventional and cholangioscopy-guided sampling of indeterminate biliary lesions at the time of ERCP: a prospective, long-term follow-up study, Peter Draganov et al, GIE, Vol. 75 (2); February 2012.

Clinical Data Highlights

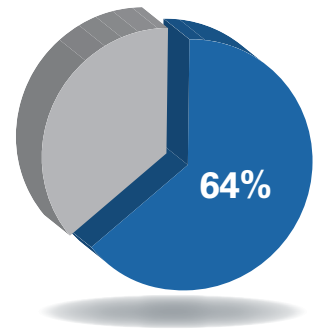
First Generation SpyGlass™ System

Since the launch of the SpyGlass Direct Visualisation System in 2007, more than 50,000 procedures have been performed and over 150 articles published – further documenting its clinical significance as an extension of the ERCP procedure.

Clinical Registry

297 Patients, 15 Centers, Yang Chen, MD, et al, *GIE*, Vol. 74, 2011

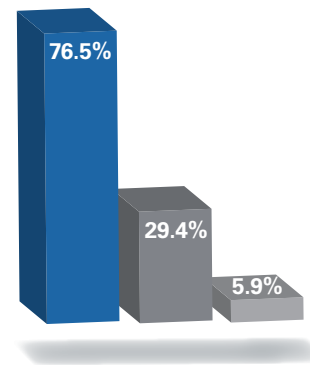
Key Results: Clinical management was altered in **64% of patients** undergoing diagnostic procedures during ERCP using cholangioscopy with the SpyGlass System.



Indeterminate Stricture Diagnosis

26 Patients, Peter Draganov, MD, et al, *GIE*, Vol. 75(2), 2012

Key Results: Demonstrated **76.5%** sensitivity using SpyBite™ Forceps performing cholangioscopy with the SpyGlass System vs **29.4%** sensitivity using blind biopsy and **5.9%** sensitivity using brushings.



Stone Management

108 Patients, Takao Itoi, MD, et al, *Digestive Endoscopy*, Vol. 22, S1, 2010

Key Results: **24% of patients** had residual stones missed on standard ERCP without cholangioscopy.

64 patients, Amit Maydeo, MD, et al, *GIE*, Vol. 74(6), 2011

Key Results: Demonstrated **83.3% stone clearance** in a single ERCP session.

Ordering Information

SpyGlass™ DS System

Order Number	Product Description
M00546650	SpyGlass DS Digital Controller
M00546600	SpyScope™ DS Access & Delivery Catheter



SpyGlass DS Accessory Devices

Order Number	Product Description	Cable Diameter	Jaw Outer Diameter	Jaw Opening	Working Length	Required Endoscope Working Channel
M00546270	SpyBite™ Biopsy Forceps	0.039"/1.0mm	1.0mm	4.1mm/55°	270cm	1.2mm
M00546451	Irrigation Tubing Set (box 10)	-	-	-	-	-

Early Physician Feedback



"The enhanced image quality is the most important improvement made to the SpyGlass DS System. This key feature could potentially help us to detect changes in vascular patterns and therefore differentiate between inflammatory and neoplastic disease."

Very important also is:

- *The quick and easy set-up of the system that makes it possible to use it mid-procedure without relevant delay*
- *The single-use design of the SpyScope that makes malfunctions very unlikely*
- *The overall improved maneuverability that allows deep cannulation into the intrahepatic ducts even in diffuse biliary disease"*

– Dr. Dechene

Universitätsklinikum Essen, Germany

"With SpyGlass DS the treatment of difficult stones has become faster, safer and more efficient overall. The improved image quality, the addition of the suction feature and the overall enhanced stability of the SpyScope will allow us to treat gallstone disease in a single setting with very high success rates."

– Dr. Sturgess

Aintree Hospital, Liverpool UK

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