SpyGlass™ DS
Direct Visualisation System

You’re going to want to see this™
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%)

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

†Compared to the first generation SpyGlass Direct Visualisation System
*GIE, October 2011
**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

**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

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* Vs first generation SpyGlass System
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

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.

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


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

Indeterminate Stricture Diagnosis


**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


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


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

SpyGlass™ DS System

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Product Description</th>
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</thead>
<tbody>
<tr>
<td>M00546650</td>
<td>SpyGlass DS Digital Controller</td>
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<tr>
<td>M00546600</td>
<td>SpyScope™ DS Access &amp; Delivery Catheter</td>
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SpyGlass DS Accessory Devices

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<tr>
<th>Order Number</th>
<th>Product Description</th>
<th>Cable Diameter</th>
<th>Jaw Outer Diameter</th>
<th>Jaw Opening</th>
<th>Working Length</th>
<th>Required Endoscope Working Channel</th>
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</thead>
<tbody>
<tr>
<td>M00546270</td>
<td>SpyBite™ Biopsy Forceps</td>
<td>0.039”/1.0mm</td>
<td>1.0mm</td>
<td>4.1mm / 55°</td>
<td>270cm</td>
<td>1.2mm</td>
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<td>M00546451</td>
<td>Irrigation Tubing Set (box 10)</td>
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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

Contact your local Boston Scientific representative for more information.