SpyGlass™ DS
Direct Visualization System

You’re going to want to see this.™
Does reliance upon two dimensional, black and white imaging (fluoroscopy) enable the most effective way to diagnose and treat pancreaticobiliary strictures and stones?

The SpyGlass DS System allows you to realize the benefits of cholangiopancreatoscopy 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%) for large or difficult stone removal

*GIE, October 2011
**Enhanced Visualization**

- **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

**SpyGlass™ System image**

**SpyGlass DS System image**

**Improved Usability**

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

**SpyGlass DS System image**

**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

* 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 visualization throughout the pancreatico-biliary system.

Sensitivity
Shown to be more than 1.6 times greater for targeted biopsies taken under direct visualization compared to brushing or fluoro-guided biopsy alone.²

Specifications
• 1mm outer diameter
• Biopsy cup: 4.1mm opening at 55º
• 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.

Contact your local Boston Scientific representative for more information.

² 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 (D); February 2012.
Clinical Data Highlights

First Generation SpyGlass™ System
Since the launch of the SpyGlass Direct Visualization 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

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


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.
Early Physician Feedback

*I’m extremely pleased with the overall functionality of the new SpyGlass DS System. It was quick and easy to set up (‘plug and play’), the image quality and stability excellent, and the four-way tip deflection intuitive. The system now enables endoscopists with ERCP expertise to perform cholangioscopy with or without intervention. My expectation is that this technology will increase our ability to diagnose and treat pancreatobiliary diseases and reduce the number of repeat ERCPs.*

- Robert Hawes, MD, FASGE
  The Center for Interventional Endoscopy at Florida Hospital
  Orlando, Florida

*I could potentially treat gallstone disease in that first setting and spare the patient a second procedure down the road which I think adds tremendous value to the system as well as, of course, to the patient and their family.*

- Gregory Cote, MD, MS
  Medical University of South Carolina
  Charleston, South Carolina