

SpyGlass™ DS Direct Visualization System

Introduction

Each year, more than one million people worldwide undergo endoscopic retrograde cholangiopancreatography (ERCP) to diagnose diseases in the biliary and pancreatic anatomies, clarify abnormal results from CT or endoscopic ultrasound (EUS), and treat conditions of the biliary ducts and pancreas.¹ The most common symptoms in patients indicated for ERCP include abdominal pain, weight loss, jaundice, or a non-definitive ultrasound or CT scan showing choledocholithiasis (i.e. 'stones') or a non-specific mass within or adjacent to the hepatobiliary tract.²

ERCPs are performed by injecting a contrast material into the pancreatic or biliary ducts and visualizing the anatomy by fluoroscopic x-ray imaging. In some cases, such as indeterminate strictures or large, impacted (difficult) stones, fluoroscopic x-ray visualization may not be sufficient. In these situations, cholangioscopy or pancreatoscopy procedures may be performed, providing **direct visualization** and treatment in the pancreaticobiliary anatomies. It is well-documented that direct visualization of the bile and pancreatic ducts during ERCP can be of significant value in helping to obtain better biopsy specimens and more effectively guide stone therapy¹ to:

- › Provide additional diagnostic information which can **alter clinical management in up to 64% of patients**¹
- › Enable more timely and **more definitive cancer diagnoses from biopsies, with twice the sensitivity**^{3*}
- › Increase **stone therapy procedure success rates to greater than 90%**¹
- › Provide **operational efficiencies** to benefit the patients and health care providers

In 2007, the fiberoptic SpyGlass™ Direct Visualization System (Boston Scientific, Marlborough, MA; USA) was introduced and addressed limitations of earlier devices. SpyGlass was the first and only single-operator cholangioscopy system – enabling optically-guided diagnostic and therapeutic procedures for stricture and stone management.

The next generation SpyGlass DS System, launched in 2015, is a digital-imaging system designed to optimize procedural efficiency and productivity with improved setup, ease of use and image quality. The SpyGlass DS System delivers enhanced visualization and image quality through a digital sensor with 4x resolution and 60% wider field of view^{***}, LED illumination, and dedicated aspiration and irrigation channels to clear the field – all integrated into the 10.5Fr SpyScope™ Catheter tip. Since its launch in 2015, the SpyGlass DS System has impacted more than 29,000 patient lives in more than 50 countries.

The SpyGlass DS System is the first minimally invasive, single operator, single-use digital cholangioscope on the market.



Potential Clinical and Economic Benefits

Managing Biliary Stones Efficiently

Approximately 10-15% of biliary stone cases are considered difficult and cannot be treated effectively using standard ERCP techniques.⁴ Electrohydraulic Lithotripsy (EHL) is a technique to manage difficult stones using a generator and bipolar probe to create a 'micro-shockwave' to fragment the stone and facilitate removal. The SpyGlass™ DS System combined with lithotripsy devices such as the Autolith Touch System for EHL provides the capability to fragment biliary stones under direct visualization, which helps to enable an increased stone clearance success rate¹ in single session treatments.*

Direct visualization stone clearance utilizing EHL has been shown to be clinically effective with **demonstrated procedural success in 90% of patients, with single-session stone clearance rates of 76%**.⁵ For biliary stone cases not addressed with conventional ERCP techniques, the Autolith Touch EHL Probe when used with the SpyGlass DS Direct Visualization System can provide the following economic benefits:

- The American Society of Gastrointestinal Endoscopy found that “EHL is effective and relatively inexpensive” compared to the alternatives.⁶ The capital cost, and ongoing service costs related to Laser Lithotripsy are significantly higher than EHL. From a capital perspective, **EHL could be as much as 86% less expensive than alternatives**.⁶
- Registry data shows that 86% of patients undergoing a SpyGlass procedure had a previous ERCP—30% of which had greater than 3 previous ERCPs.¹ **Access to a full time difficult stone solution such as the Autolith Touch provides a critical tool to resolve the stone in the index procedure.** This may lead to greater patient satisfaction and avoided patient referrals and leakage.¹

Achieving single session stone clearance and reducing the need for a repeat procedure(s) may deliver greater patient satisfaction and decrease unnecessary procedural costs. Furthermore, by enabling clinicians to manage difficult stone cases they may be able to avoid patient leakage/referrals which may minimize the risk of lost subsequent payment.

Indeterminate Biliary Stricture Cases and Diagnosing Malignancy

The **SpyGlass DS System enables faster, more accurate cancer diagnosis by increasing biopsy sensitivity more than 2 times when compared to fluoroscopic guided biopsy**.^{1,3} Current diagnostic techniques (CT, EUS, ERCP) may be unable to produce definitive diagnoses. This may promote ongoing tests, contributing to overall costs of care and consuming valuable time which may further compromise the patient's available treatment options.

Current ERCP tissue sampling techniques include cytology brushing (5.8% sensitivity) and fluoroscopic biopsy (29.4% sensitivity).⁷ Performing biopsies under direct visualization using the **SpyGlass System** and **SpyBite™ Biopsy Forceps** (66% sensitivity¹)¹ enables **faster, more accurate diagnosis** of malignancies. Studies utilizing cholangioscopy with the SpyGlass System¹ have demonstrated that clinical management was altered in 64% of patients, including changes to stricture management in 69% and the decision to perform surgery in 25%.

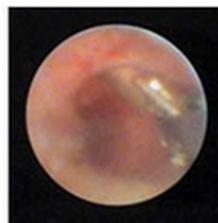
Boston Scientific is the co-exclusive distributor of the Autolith™ Touch EHL System, which provides opportunities to streamline vendor management for ERCP supplies while expanding the high caliber of Boston Scientific sales support to EHL.

Image Comparison

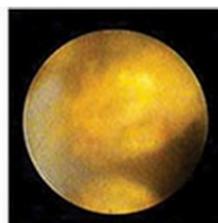
First Generation System

SpyGlass DS System

BIOPSY



STONE



The increased likelihood of definitively diagnosing patients within a hospital system, rather than referring a patient elsewhere, may provide later benefits to the hospital. This is because the patient may be more likely to stay within the diagnosing hospital system to receive any needed treatment.

Operational Efficiencies

The SpyGlass™ DS System offers operational benefits contributing to efficiency and reducing procedure time. The system has a fixed imager for responsive steering and increased maneuverability, which can help aid clinicians to quickly direct the scope to the target anatomy. Similarly, a 1.2mm working channel and enhanced exit port facilitate efficient and timely device exchange.

Additional efficiencies are realized through the “plug-and-play” setup due to the automatic white balance and focus. In testing, estimated **set-up time was cut by ~80%** compared to the first generation SpyGlass System (from 23 min to 5 min). If SpyGlass set-up is called for mid-procedure, these efficiencies may result in patient benefits due to **reduced anesthesia time while both the patient and clinician benefit from reduced fluoroscopy exposure**. The integrated controller offers increased accessibility and saves lab storage space, because it fits on a standard ERCP cart.



SpyGlass DS Digital Controller fits on a standard ERCP cart

The SpyGlass DS System’s Access & Delivery Catheter is intended for single-use, eliminating the potential for contamination from reuse, while eliminating staff time spent on probe reprocessing.

Economic Impact	
Dollar impact for every \$1 invested in SpyGlass DS System	3.1
Dollars of net impact for every \$1 invested in SpyGlass DS System	1.2
Net Impact of SpyGlass System Investment	
Net Impact	32%

Sample Output From SpyGlass DS Hospital Impact Model Calculator

Conclusion

- › The SpyGlass DS System provides important clinical, operational and economic benefits for managing patients with difficult stones and indeterminate biliary strictures. Benefits of the SpyGlass DS System may include:
 - › **Clinical Management altered in 64% of patients** undergoing diagnostic ERCP with cholangioscopy using the SpyGlass System
 - › **Enables faster, more definitive cancer diagnosis** by allowing clinicians to obtain biopsies of tissue under direct visualization, improving sensitivity and diagnostic yield

- › Patients who are definitively diagnosed within a hospital system may be **more likely to stay with and receive treatments** from the diagnosing hospital system
- › **90%+ stone therapy procedure success rates reduce the need for follow up procedures**, which may have a significant impact on patient outcomes and patient satisfaction
- › **Enables clinicians to manage difficult stone cases without referring out**, this minimizes the risk of lost subsequent payment due to compromised patient retention
- › Provides operational efficiencies; for example, if setup is performed mid-procedure, reduced set up time shortens overall anesthesia time, while **both the patient and clinician benefit from reduced fluoroscopy exposure**

* Compared to cytology brushing

** Compared to balloon retrieval

***Compared to the first generation SpyGlass System

† 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.¹

Sources

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8. O'Neill et al. Costs and Trends in Pancreatic Cancer Treatment. *Cancer*; October 15, 2012:5132-5139.

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