



See and enable diagnosis and treatment of bile duct disease with the SpyGlass™ DS II Direct Visualization System

The SpyGlass DS II System enables high-resolution imaging and therapy during an ERCP procedure to target biopsies and fragment stones. This may result in effective evaluation, help avoid the need for additional testing and repeat procedures, and enable patients to receive timely diagnosis and treatment. In a retrospective study, ERCP with cholangioscopy was associated with a decrease in costs compared to ERCP alone!¹



See.

In a study, direct visualization of indeterminate biliary strictures using the SpyGlass DS II System influenced patient management by identifying causes of bile duct stricture?²

The study showed:

- Visualization of stricture in 98.6% of subjects²
- Adequate biopsies in 92.9% of cases²



98.6%
Visualization²
SHOWN IN STUDY

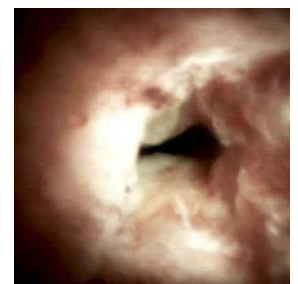
Diagnose.

A study showed that performing biopsies under direct visualization using the SpyGlass DS II System and SpyBite™ Biopsy Forceps may enable more definitive diagnosis of malignancies through increased sensitivity³ compared to brush cytology.⁴

The study showed:

- Targeted biopsy yielded 86% sensitivity and 100% specificity³

In a randomized clinical trial, SpyGlass DS II System-guided biopsy sample sensitivity was significantly higher than ERCP-guided brushing. (68.2% vs. 21.4%; p<01)⁵



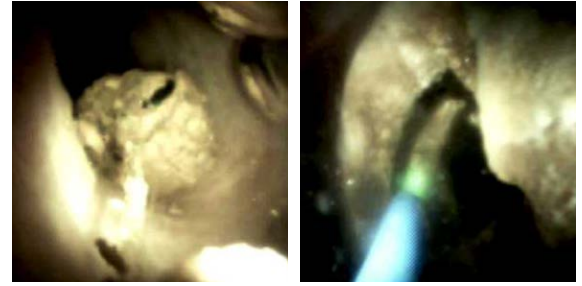
86%
Sensitivity and
100%
Specificity³
SHOWN IN STUDY

Treat.

In a randomized clinical trial, cholangioscopy-guided laser lithotripsy increased the removal of bile duct stones compared to conventional therapies.⁶

– SpyGlass DS II System-guided lithotripsy resulted in 93% of study patients with successful stone clearance vs. 67% clearance with traditional treatments such as mechanical lithotripsy and balloon dilation without direct visualization⁶

In a retrospective analysis, biliary stone clearance in a single procedure was achieved in 83.1% of patients – eliminating the need for a follow-up procedure to remove residual stones.⁷



93% Stone clearance⁶
SHOWN IN CLINICAL TRIAL

Want more clinical data?

Go to [bostonscientific.com/cholangioscopy](https://www.bostonscientific.com/cholangioscopy) to see all of the SpyGlass DS II Visualization System case studies and clinical data.

1. Results from a comparative study where a total of 51 patients (35 female) with a mean age of 66 years underwent 58 SOPOC procedures. The average cost of ERCP with cholangioscopy was \$4550 vs. \$7766 in open common bile duct exploration and \$6175 in laproscopic common bile duct exploration* demonstrated in Sandha J, Sandha GS. Tu1536 Single-operator cholangioscopy is more cost-effective than bile duct exploration for management of difficult common bile duct stones after failed conventional ERCP. *Gastrointest Endosc.* 2016;83(Suppl 5):AB599.
2. Almadi MA, Itoi T, Moon JH, et al. Using single-operator cholangioscopy for endoscopic evaluation of indeterminate biliary strictures: results from a large multinational registry. *Clinical Study. Endoscopy.* 2020;52:574–582.
3. 86% sensitivity of DSOC demonstrated in Shah RJ, Rajjman I, Brauer B, Gumustop B, Pleskow DK. Performance of a fully disposable, digital, single-operator cholangiopancreatoscope. *Clinical Study. Endoscopy.* 2017;49:651–658.
4. Results from a comparative study where the pooled sensitivity and specificity of brushings for the diagnosis of malignant biliary strictures was 45% (95% confidence interval [CI], 40%–50%) and 99% (95% CI, 98%–100%), respectively* demonstrated in Navaneethan U, Zhu X, Lourdasamy D, Lourdasamy V, Vardarajulu S. Sa1378 Comparative effectiveness of various ERCP based modalities for detection of malignant biliary strictures. *Gastrointest Endosc.* 2017;85(Suppl 5): AB216–AB217.
5. Results from a comparative study where the first sample sensitivity of DSOC-guided biopsy samples was significantly higher than ERCP-guided brushing (SA 68.2% vs CA 21.4%, $P < .01$)* demonstrated in Gerges C, Beyna T, Tang RSY, et al. Digital single-operator peroral cholangioscopy guided biopsy sampling versus ERCP-guided brushing for indeterminate biliary strictures: a prospective, randomized, multicenter trial (with video). *Gastrointest Endosc.* 2020;91:1105–1113.
6. Results from a comparative study where endoscopic clearance was achieved in 39 (93%) of 42 patients treated with cholangioscopy-guided laser lithotripsy and 12 (67%) of 18 treated with conventional therapy only ($P = .009$)* demonstrated in Buxbaum J, Sahakian A, Ko C, et al. Randomized trial of cholangioscopy-guided laser lithotripsy versus conventional therapy for large bile duct stones (with videos). *Clinical Study. Gastrointest Endosc.* 2018;87:1050–1060.
7. Seoud T, Syed A, Kantamaneni V, et al. Diagnostic and therapeutic utility of spyglass digital probe in the evaluation and treatment of pancreatobiliary disorders. *Am J Gastroenterol.* 2020;115 (Suppl):S1696. 2020 Annual Scientific Meeting of the American College of Gastroenterology, ACG 2020.

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