With over 300 articles published to date, it is well documented that direct visualization of the bile ducts by peroral cholangioscopy can be of value in the diagnosis of biliary abnormalities, obtaining biopsy specimens, and guiding stone therapy.¹

- First use of peroral cholangioscopy reported in the 1970s
- Adoption significantly hampered over the next 30 years due to technical limitations of ‘mother-baby’ cholangioscopes including:
  - Fragility resulting in high repair costs
  - Limited steerability
  - Poor irrigation capabilities
  - Requires 2 operators

The SpyGlass System was developed to:
- Overcome the limitations of traditional cholangioscopes
- Provide optically-guided therapeutics for targeted stricture and stone management

FIRST single-operator cholangioscopy (SOC) system:
- 10Fr SpyScope™ Access & Delivery Catheter with:
  - Two dedicated irrigation channels
  - Optic channel
  - 1.2mm diameter therapeutic channel
  - 4-way tip deflection to facilitate steerability through small ducts

Innovation is continuing...

SpyGlass™ System Timeline

1st Documented use of ‘mother-baby’ cholangioscope

Pre-clinical study published GIE1

SpyGlass System Launched

2007

2009

25,000 cases
60+ publications
600 systems

50,000 cases
150+ publications
1,000 systems

Clinical Registry in GIE - 297 patients - largest study of peroral cholangioscopy2

AMEA* clinical registry: Targeting 25 sites, 500 patients, 12 countries

Innovation is continuing...


2 Single-operator cholangioscopy in patients requiring evaluation of bile duct disease or therapy of biliary stones (with videos), Yang Chen et al. GIE, Vol 74, Issue 4, October 2011.

*Asia, Middle East and Africa
## Pre-Clinical & Clinical Registry Results

<table>
<thead>
<tr>
<th>Journal Article</th>
<th>Authors</th>
<th>Study Type</th>
<th>Publication</th>
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</tr>
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<tbody>
<tr>
<td>1 Pre-clinical characterization of the SpyGlass™ peroral cholangiopancreatoscopy system for direct access, visualization and biopsy</td>
<td>Yang Chen et al</td>
<td>Lab simulation &amp; observational investigation, single user</td>
<td>GIE, Vol. 65, No. 2: February 2007</td>
<td>The SpyGlass System allows access and biopsy targeting</td>
</tr>
<tr>
<td>3 Single-operator cholangioscopy in patients requiring evaluation of bile duct disease or therapy of biliary stones (with videos)</td>
<td>Yang Chen et al</td>
<td>Prospective clinical cohort study</td>
<td>GIE, Vol. 74, Issue 4, October 2011</td>
<td>• 297 patients • 64% altered patient management • 92% stone success • 66% sensitivity</td>
</tr>
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## Evaluation of Clinical Utility of SpyGlass System

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<thead>
<tr>
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<th>Key Data</th>
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<tbody>
<tr>
<td>4 Prospective evaluation of the clinical utility of ERCP-guided cholangiopancreatoscopy with a new direct visualization system.</td>
<td>Peter Draganov et al</td>
<td>Prospective cohort study</td>
<td>GIE, Vol. 73, Issue 5, May 2011</td>
<td>• 75 patients • 14.2 min mean SpyGlass System visualization time • 5 min mean setup time</td>
</tr>
</tbody>
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## Indeterminate Stricture Diagnosis

<table>
<thead>
<tr>
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</table>
| 5 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     | Prospective, long-term follow-up, paired design cohort study | GIE, Vol. 75 (2); February 2012 | 26 patients  
76.5% sensitivity SpyBite™ Forceps vs. 29.4% blind biopsy & 5.9% brushings |
88% sensitivity                                                              |
| 7 Role of single-operator peroral cholangioscopy in the diagnosis of indeterminate biliary lesions: a single-center, prospective study | Mohan Ramchandani et al  | Prospective, single-arm, single-center study | GIE, Vol. 79 (6), June 2014        | 36 patients  
95% cholangioscopic impression for malignancy  
82% SpyBite Forceps differentiating intent-to-treat |

## Stone Management

<table>
<thead>
<tr>
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</table>
| 8 Evaluation of Residual Bile Duct Stones by Peroral Cholangioscopy in Comparison with Balloon Cholangioscopy | Takao Itoi et al         | Retrospective | Digestive Endoscopy, Vol. 22, S1, June 2010 | 108 patients  
24% residual stones missed on standard ERCP  
Risk factors: large bile duct, juxtapapillary diverticulum, use of ML or EHL |
| 9 Single-operator cholangioscopy-guided laser lithotripsy in patients with difficult biliary and pancreatic ductal stones (with videos) | Amit Maydeo et al        | Prospective | GIE, Vol. 74(6), December 2011    | 64 patients  
83.3% single session clearance  
Inclusion criteria: Difficult bile duct stones not amenable to treatment by mechanical lithotripsy and/or balloon sphincteroplasty. |
| 10 Single-operator cholangioscopy for the extraction of cystic duct stones (with video) | Paul Sepe et al          | Retrospective | GIE, Vol. 75(1), January 2012     | 13 patients  
76.9% complete clearance  
Inclusion criteria: Cystic duct stones |
Resources

SpyGlass™ System
Brochure
ENDO-61903-AB

SpyGlass System
Clinical Registry
Results Brochure
ENDO-61904-AB

SpyGlass System
Pancreateto-biliary
Atlas
SME15390

SpyGlass System
Clinical Registry
iFolio
ENDO-99801-AA

Tap on to view each resource