SpyGlass™ DS II
Direct Visualization System and Accessories

Does reliance upon two dimensional, black and white imaging (fluoroscopy) enable the most effective way to diagnose and treat pancreaticobiliary strictures and stones?

**Fluoroscopic vs cholangioscopic views of a malignant biliary stricture**

Stephen Kim, M.D.,
Los Angeles, CA, Diagnosis: Malignant Biliary Stricture

**Fluoroscopic vs cholangioscopic views of a Cholangiocarcinoma, Biopsy with the SpyBite Max under direct visualization**

Isaac Raijman, M.D.,
Houston, TX, Diagnosis: Cholangiocarcinoma

**SpyGlass™ DS II System allows you to realize the benefits of cholangio-pancreatoscopy as an extension of the ERCP procedure and new standard of care.**

The latest prospective literature* about the SpyGlass™ Direct Visualization System demonstrated:

- High diagnostic accuracy, ranging from 84% to 95%1
- High success rate of 82% to 93% for removing large or difficult stones1,2
- A reduction of the number of procedures and associated costs when SpyGlass is used in the first diagnostic ERCP or during the first mechanical lithotripsy session3

**SpyGlass™ DS II System**

- **Fluoroscopic Cytology Brush**
- **First Generation SpyGlass™ System**
- **SpyGlass™ DS System with SpyBite™**
- **SpyGlass™ DS II System with SpyBite™ Max**

<table>
<thead>
<tr>
<th>System</th>
<th>Sensitivity</th>
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<tbody>
<tr>
<td>Fluoroscopic Cytology Brush</td>
<td>30%</td>
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<tr>
<td>First Generation SpyGlass™ System</td>
<td>49%</td>
</tr>
<tr>
<td>SpyGlass™ DS System with SpyBite™</td>
<td>86%</td>
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</table>

* The latest prospective literature refers to the most recent research conducted in this field.

**WHETHER CASES ARE SIMPLE OR COMPLEX, THE STANDARD OF CARE SHOULD BE ANYTHING BUT STANDARD**
A History of Innovation in Cholangioscopy

First documented use of "mother-baby" cholangioscopy: 1970
Launch of the First Generation SpyGlass™ System and SpyBite™ Biopsy Forceps: 2007
Launch of the next generation SpyGlass™ DS System: 2015
Winner - Silver MEDA Award in the Radiological and Electromechanical Devices category: 2016
Exclusive distribution with Northgate Technologies, enabling access of EHL globally*: 2017
Launch of the SpyGlass™ DS II System and the SpyGlass™ Retrieval Basket and Snare: 2019
Launch of the SpyBite™ Max: 2020

Since its launch in 2015, the SpyGlass DS System has impacted more than 110,000 patients' lives, and has been used in more than 2,200 hospitals across more than 65 countries.

**SpyGlass™ DS Digital Controller**
- Set-up time under 5 minutes
- Equipment designed to fit on a standard endoscopy cart
- Automatic white balance and focus
- Existing SpyGlass DS Controllers only require a new software installation to use the SpyScope DS II Delivery and Access catheter

**SpyGlass™ DS II Direct Visualization System**
- New larger CMOS chip featuring increased resolution, 2.5x that of the SpyScope DS Catheter
- HDR processing to reduce light flare, improve lighting in the corners of the video and enhance the view down the lumen

**SpyBite™ Max Biopsy Forceps**
- Larger fenestration holes for top and bottom jaws
- Larger front serrated teeth
- Serrated teeth side profile on average
- Increased cup volume

**Image from the second generation Spyscope DS Delivery and Access catheter**
- Single-use sterile catheter
- Automatic light control & LED illumination
- Dedicated irrigation and aspiration connections to clear field of view

**Image from the third generation Spyscope DS II Delivery and Access catheter**
- Dedicated irrigation and aspiration connections to clear field of view

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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
Providing More Solutions for Better Patient Care With Cholangioscopy

EHL and Holmium Laser
Both EHL and Holmium Laser may be used in conjunction with the SpyGlass™DS II System to manage large biliary stones. The Autolith Touch EHL generator and probes are distributed by Boston Scientific.¹

SpyGlass™ Retrieval Snare
This snare is intended to be used with the SpyGlass™DS II System to remove foreign bodies like migrated plastic stents. It is made with two Nitinol wires and a PEEK sheath which allow to open even in small and tortuous locations like intra-hepatic, cystic or pancreatic ducts.

Specifications
- 1mm OD catheter
- 5mm diameter snare
- 2 Nitinol wires
- Single use, not a hot snare

SpyGlass™ Retrieval Basket
This basket is intended to be used with the SpyScope™ SpyGlass™DS II System to effectively achieve complete ductal clearance under direct visualization in a single session. The basket allows to remove foreign bodies like migrated plastic stents, stones or stone fragments after EHL/Laser lithotripsy or missed on a cholangiogram. It is made with Nitinol wires and a PEEK sheath which allow to open even in small and tortuous locations like intra-hepatic, cystic or pancreatic ducts.

Specifications
- 1mm OD catheter
- 75mm diameter basket to catch stones from 3-10mm
- 8 Nitinol wires
- Single use, not mechanical lithotripsy compatible

SpyBite™ Max Biopsy Forceps
The SpyBite Max Biopsy Forceps are intended to be used with the SpyGlass™DS II System to enable targeted specimen sampling under direct visualization throughout the pancreatic-biliary system.

Diagnostic Accuracy
Cholangioscopy-guided biopsies of indeterminate biliary lesions with SpyBite have significantly higher accuracy compared with ERCP-guided cytology brushings and standard forceps biopsies.²

Specifications
- 1mm outer diameter
- Biopsy cup: 4.1mm opening at 5º

SpyBite Max acquires more than twice the amount of tissue as compared to SpyBite

ExpertCare Service Programs
Protect your investment and experience peace of mind
- Improve quality of care while reducing cost and maintaining operational performance
- Minimize downtime
- Access knowledge of our ExpertCare engineers With Evercare, always get the latest software version for your SpyGlass DS Digital controller.

Specifications
- Unlimited technical support calls
- 24/7 access to technical support
- Unrestricted in-house service repair and parts coverage
- Software updates and upgrades during the contract period

Ordering information

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material is intended for United States healthcare professionals only.

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