

# SpyGlass™ DS II

Direct Visualization System Accessories



*You're going to want to see this.™*



WHETHER CASES ARE SIMPLE OR COMPLEX, THE STANDARD OF CARE SHOULD BE ANYTHING BUT STANDARD

## 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

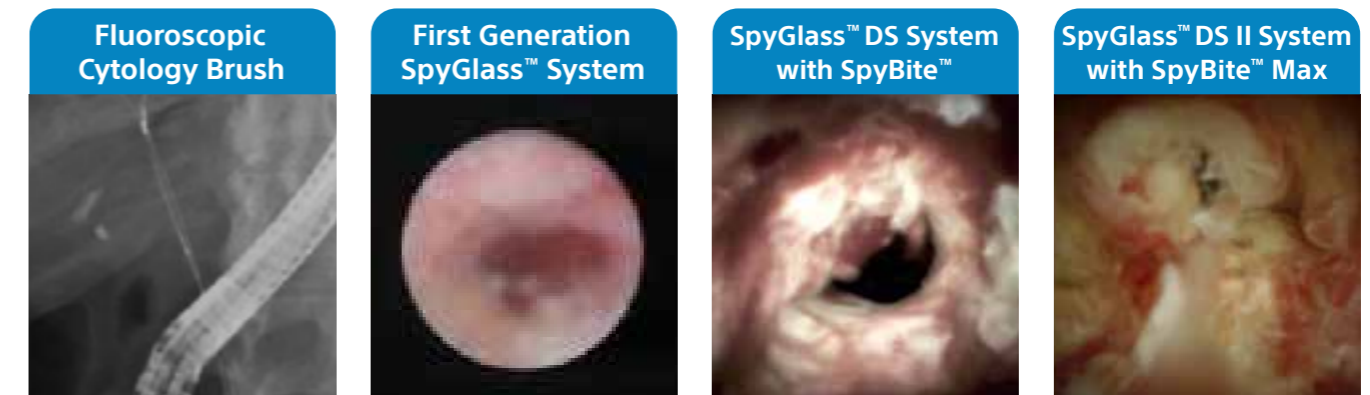
Isaac Rajjman, M.D.,  
Houston, TX, Diagnosis: Cholangiocarcinoma



**SpyGlass™ DS II System allows you to realize the benefits of cholangio-pancreatography 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%<sup>1</sup>
- High success rate of 82% to 93% for removing large or difficult stones<sup>1,2</sup>
- 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 session<sup>3</sup>

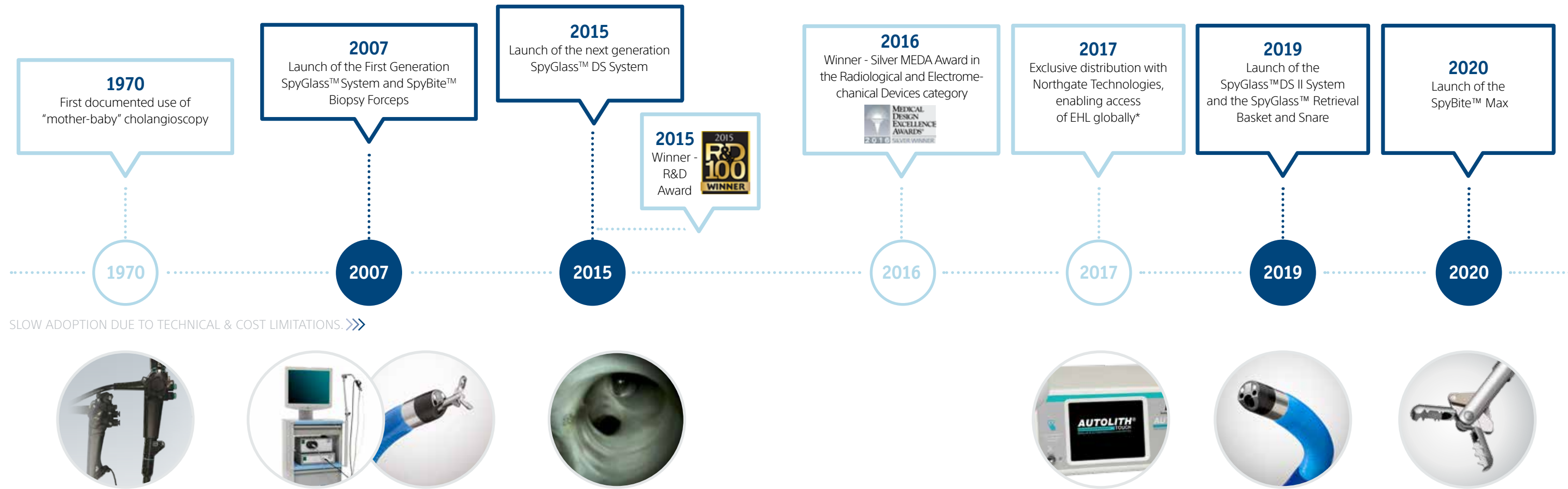


Sensitivity  
**30%**

Sensitivity  
**49%**

Sensitivity  
**86%**

# A History of Innovation in Cholangioscopy



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.

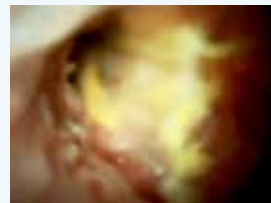
**2015** Digital + Simple = SpyGlass™ DS Direct Visualization System

Image from the second generation of 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



SPYSCOPE DS CATHETER



SPYSCOPE DS CATHETER VIEW

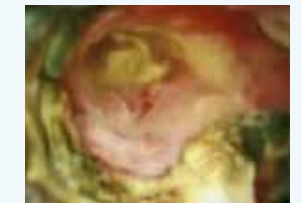
**2019** Digital + Simple x 2 1/2 INCREASED RESOLUTION = SpyGlass™ DS II Direct Visualization System

Image from the third generation of Spyscope DS II Delivery and Access catheter

- **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



SPYSCOPE DS II DELIVERY AND ACCESS CATHETER



SPYSCOPE DS II CATHETER VIEW

**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



**2020** x2 THE AMOUNT OF TISSUE AS COMPARED TO SPYBITE<sup>4</sup> = SpyBite™ Max Biopsy Forceps

**A design enhancement to the legacy SpyBite™ Biopsy Forceps:**

- Larger fenestration holes for top and bottom jaws
- Larger front serrated teeth
- Serrated teeth side profile on average
- Increased cup volume





# Providing More Solutions for Better Patient Care With Cholangioscopy



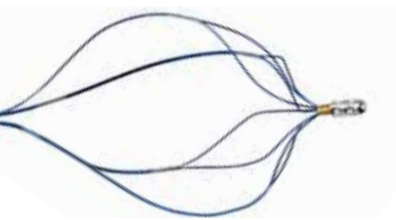
## EHL and Holmium Laser

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.<sup>4</sup>



## 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**.



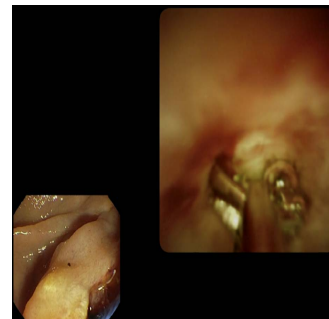
## SpyGlass™ Retrieval Basket

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**.

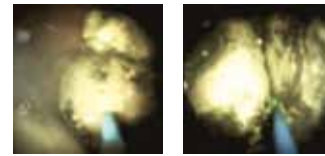


## SpyBite™ Max Biopsy Forceps

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 pancreato-biliary system.



Mankanwal Sachdev, MD, Cholangioscopy guided biopsy of indeterminate biliary stricture



### Specifications

- 1mm OD catheter
- 9mm diameter snare
- 2 Nitinol wires
- Single use, not a hot snare

### Specifications

- 1mm OD catheter
- 15mm diameter basket to catch stones from 3-10mm
- 8 Nitinol wires
- Single use, not mechanical lithotripsy compatible

### 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.<sup>5</sup>

### Specifications

- 1mm outer diameter
- Biopsy cup: 4.1mm opening at 55°

**SpyBite Max acquires more than twice the amount of tissue as compared to SpyBite<sup>6</sup>**

## 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.

SPYGLASS™ DS DIRECT VISUALIZATION SYSTEM		
Service Plan	Evercare	Essentialcare
Unlimited technical support calls	•	•
24/7 access to technical support	•	•
48h delivery of exchange machine	•	•
Unlimited in-house service repair and parts coverage	•	•
Software updates and upgrades during the contract period	•	

AUTOLITH™ TOUCH EHL SYSTEM	
Service Plan	Essentialcare
Unlimited technical support calls	•
24/7 access to technical support	•
48h delivery of exchange machine	•
Unlimited in-house service repair and parts coverage	•

## Ordering information

PRODUCT ORDER NUMBER	PRODUCT DESCRIPTION
<b>SpyGlass™ DS II System Device</b>	
M00546610	SpyScope™ DS II Access & Delivery Catheter
<b>SpyGlass DS II™ System Capital</b>	
M00546650	SpyGlass DS II™ Digital Controller (with new software)
SRVM005SPYDIG2002	SpyGlass DS II™ Controller Image Software (to upgrade existing SpyGlass DS Controllers)
M005466800	Autolith Touch EHL Generator <sup>4</sup>
<b>SpyGlass™ DS II System Device</b>	
M00546470	SpyBite™ Max Biopsy Forceps <sup>4</sup>
M00546620	1.9 Fr., 375cm Biliary EHL Probe <sup>4</sup>
M00546550	SpyGlass™ Retrieval Basket
M00546560	SpyGlass™ Retrieval Snare
SIT-575-15	Hydra™ Irrigation Tubing (Medivators and Erbe pumps)
<b>SpyGlass Service contracts</b>	
SRVM005SPYDIG1015	Post-Sale SpyGlass Digital Evercare 3-years contract
SRVM005ATLT1007	Post-Sale Autolith Touch Essential care 3-years contract

† Compared to the first generation SpyGlass Direct Visualisation System  
\* 2017 prospective studies:

1. Laleman W1,2, Verraes K3, Van Steenberghe W3, Cassiman D3, Nevens F3, Van der Merwe S3, Verslype C3. Usefulness of the single-operator cholangioscopy system SpyGlass in biliary disease: a single-center prospective cohort study and aggregated review. Surg Endosc. 2017 May;31(5):2223-2232. doi: 10.1007/s00464-016-5221-2. Epub 2016 Sep 7.
2. Buxbaum J, Sahakian A, Ko C, Jayaram P, Lane C, Yu CY, Kankotia R, Laine L. Randomized trial of cholangioscopy-guided laser lithotripsy versus conventional therapy for large bile duct stones (with videos). Gastrointestinal Endoscopy (2017), doi: 10.1016/j.gie.2017.08.021.
3. Pierre H. Deprez1, Rodrigo Garces Duran1, TomMoreels1, Gianluca Furneri2, Federica Demma2, Len Verbeke3, Schalk W. Van der Merwe3, WimLaleman3. The economic impact of using single-operator Cholangioscopy for the treatment of difficult bile duct stones and diagnosis of indeterminate bile duct strictures. Endoscopy 2017 Nov 24. doi: 10.1055/s-0043-121268.
4. Distributed by Boston Scientific Corporation, Marlborough, Massachusetts; manufactured by Northgate Technologies Inc., Elgin, Illinois.
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, GIE, Vol. 75 (2); February 2012.
6. Data on file

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 labelling supplied with each device. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material is not intended for use in France.

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