SpyBite™ Max Biopsy Forceps for use with

SpyGlass™ DS II Direct Visualization System featuring Sight Shield Technology

Boston Scientific

The **SpyGlass DS II Direct Visualization System** with **Sight Shield Technology** is a complete direct imaging system designed for pancreaticobiliary stone and stricture management of the bile and pancreatic ducts during endoscopic retrograde cholangiopancreatography (ERCP).

SpyBite Max Biopsy Forceps

Performing biopsies under direct visualization using the SpyGlass DS System and Legacy SpyBite Biopsy Forceps may enable more definitive diagnosis of malignancies through increased sensitivity compared to brush cytology.[1,2] SpyBite Max Biopsy Forceps – a design enhancement to the Legacy SpyBite Biopsy Forceps – has been shown to acquire on average more than 2X tissue per bite.[3]

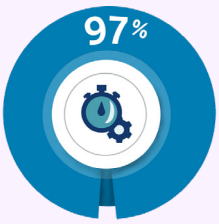
Cancer diagnosis

Conventional techniques, specifically cytology brushing, may not be able to produce definitive results. This may lead to additional tests which could contribute to increased overall costs of care and loss of time, compromising a patient's treatment options.

The SpyBite Max Biopsy Forceps feature+

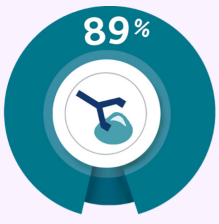
1. Larger fenestration holes for tissue acquisition
2. Increased cup volume for tissue acquisition
3. Larger front serrated teeth to prevent slipping
4. Serrated teeth on the side profile

+ Compared to Legacy SpyBite Biopsy Forceps



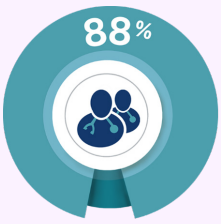
97% Tissue Acquisition Rate*

Higher tissue acquisition rate may enable more efficient procedures



89% of Physicians*

Stated SpyBite Max acquired on average more tissue per bite than Legacy SpyBite



88% of Physicians*

Were more confident in their ability to acquire tissue from challenging scope positions

* Thirty-six physicians were provided samples of SpyBite Max Biopsy Forceps and asked to evaluate the clinical performance of the device. Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary. Data on file.

SpyBite™ Max Biopsy Forceps

SpyGlass™ DS II Direct Visualization System

Order Number	Product Description	Packaging
M00546650	SpyGlass™ DS Digital Controller	Each
M00546610	SpyScope™ DS II Access & Delivery Catheter	Each

Order Number	Product Description	Cable Diameter (in/mm)	Jaw Outer Diameter (mm)	Working Length (cm)	Required Endoscope Working Channel (mm)
M00546470	SpyBite™ Max Biopsy Forceps	0.039/1.0	1	286	1.2

1. Shah et al. Performance of a full disposable, digital, single-operator cholangiopancreatoiscope. Endoscopy 2017; 49; 651-658
2. Navaneethan U, Njei B, Lourdusamy V, Konjeti R, Vargo JJ, Parsi MA. Comparative effectiveness of biliary brush cytology and intraductal biopsy for detection of malignant biliary strictures: a systematic review and meta-analysis. Gastrointest Endosc. 2015;81:168-176.
3. Twenty-five physicians acquired samples in a simulated clinical environment with ex-vivo porcine tissue using both Legacy SpyBite and SpyBite Max. Acquired tissue samples were measured and compared. Bench Test results may not necessarily be indicative of clinical performance. The testing was performed by or on behalf of BSC. Data on file.

BSC's Legacy SpyBite Forcep device has reached end of life and is not commercially available.
All photographs taken by Boston Scientific.

Caution: U.S. Federal law restricts this device 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 or at www.IFU-BSCI.com.

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