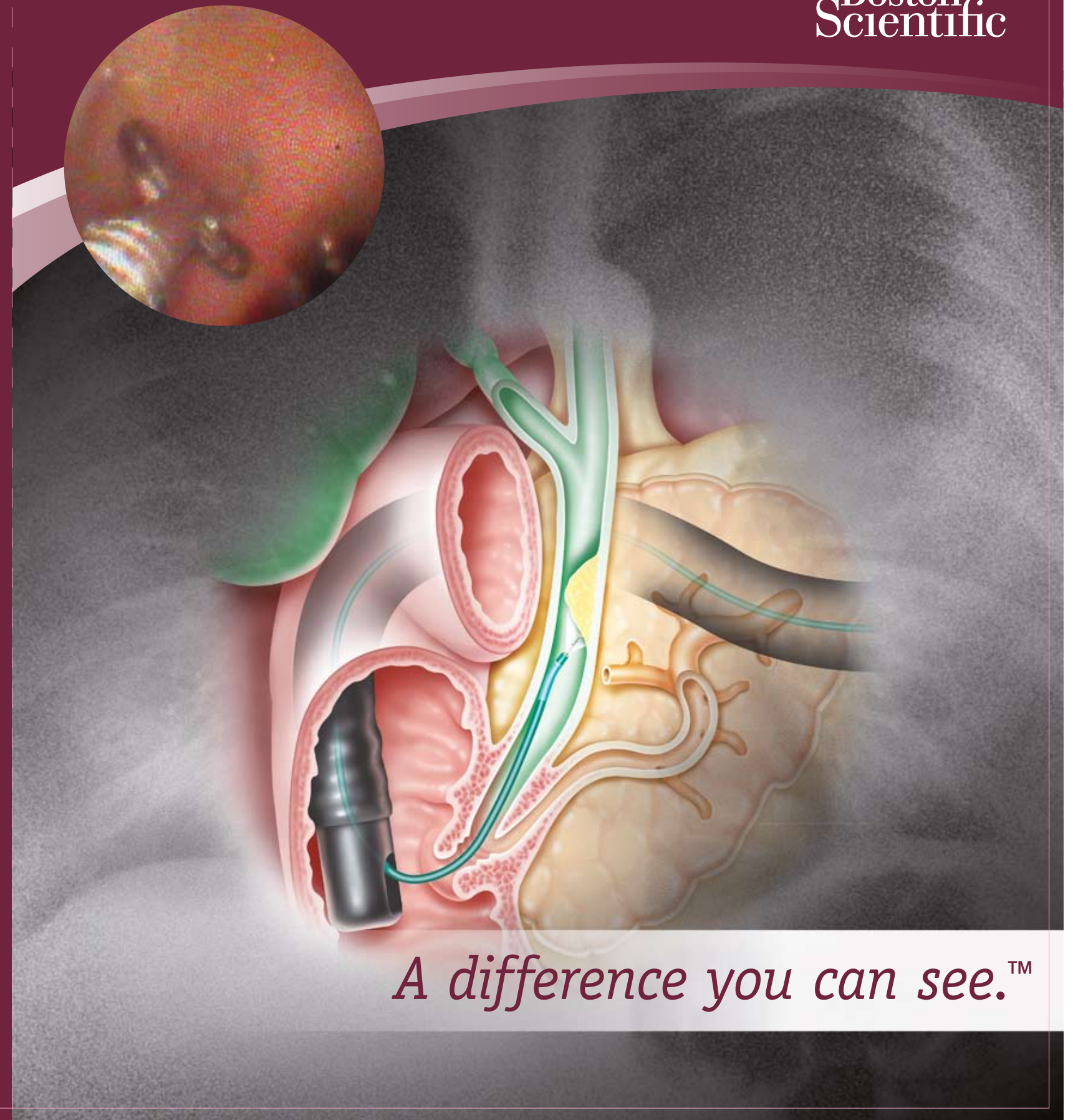


# SpyGlass™

Direct Visualisation System

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*A difference you can see.™*

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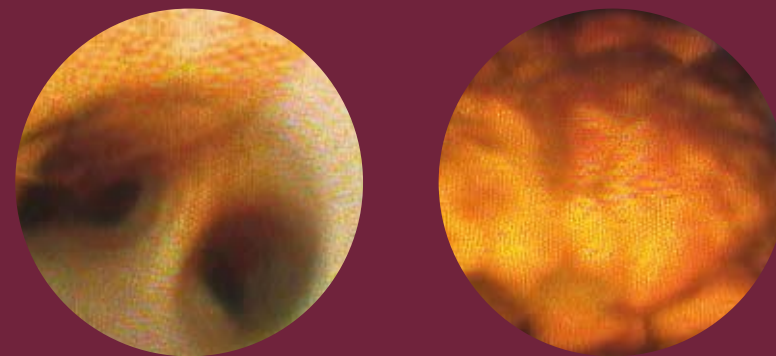
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SPYGLASS™ INTRADUCTAL IMAGES





The SpyGlass™ Direct Visualisation System is an integrated product platform that combines capital components and consumable devices to provide an intraluminal view for directing therapeutic devices within the biliary duct system.



By attaching the SpyScope™ Access and Delivery Catheter to a duodenoscope with a 4.2 mm working channel, the SpyGlass Direct Visualisation System is engineered to:

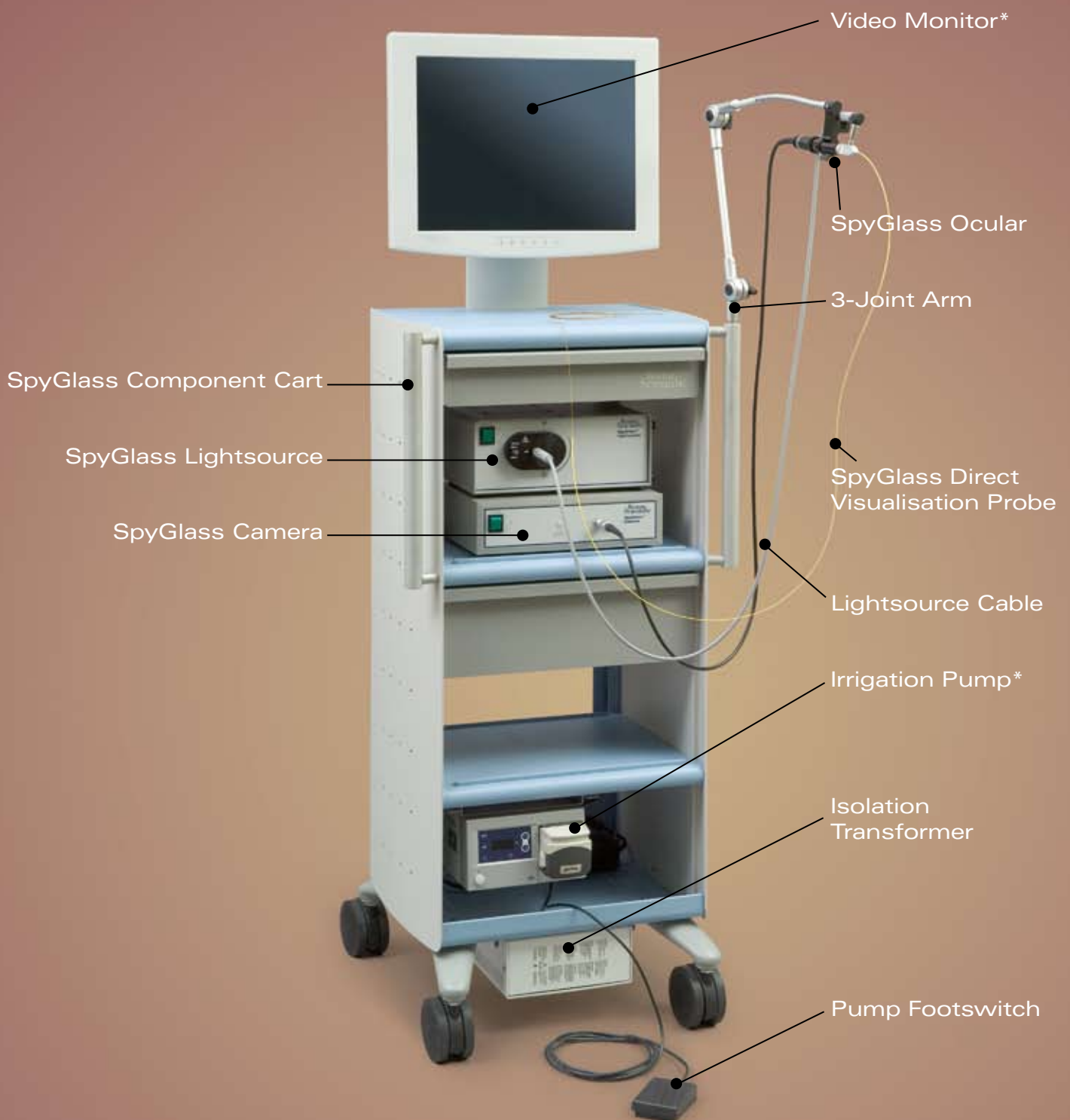
- Provide endoscopic, site specific examination and visually-guided tissue sampling for histologic examination
- Enable a complete circumferential intraluminal view beyond the papilla, potentially increasing target accessibility via the four-way steerable SpyScope Access and Delivery Catheter
- Offer single-operator control with more precise manoeuvrability, allowing additional endoscopy suite staff to focus on patient care



**Note:** Monitor and pump (pictured here and on front of this brochure) are not currently available from Boston Scientific, but are recommended for use with the SpyGlass capital.\*

\* Data on file Boston Scientific





# SpyGlass™ Direct V

## CAPITAL

### Components Cart and 3-Joint Arm

The component cart has two storage drawers and two shelves for holding individual components. The cart also has a mounting bracket for the video monitor and four casters for mobility. The 3-joint arm is supplied with the cart and has a flexible goose neck for positioning in multiple directions. There is a connector at the end of the 3-joint arm for secure attachment of the ocular.

### Lightsource and Light Cable

The lightsource is a hospital grade medical device with a 300 Watt nominal lamp. A digital time meter records and displays the internal lamp on elapsed time in hourly increments. The lightsource cable inserts into the front of the lightsource unit via a single Wolf-style port. The lightsource cable end fitting has an integral condensing lens and IR filtration (heat filtration). Light intensity can be manually increased or decreased with a control wheel (shutter).

### Camera and Camera Head

The camera is a hospital grade medical device with a 6.4 mm CCD colour image sensor. The camera is equipped with Automatic White Balance (AWB) which is activated by momentarily depressing the AWB button.

The camera beeps on AWB completion. The camera can output three types of video signals:

- Composite (BNC)
- S-video (Y-C)
- RGBS (Red-Green-Blue-Sync)

One of these signals can be used to provide a video signal to most common Electronic Medical Records (EMR) systems for electronic software reporting. The hospital facilities contact or network provider can determine which of these signals to use.

The camera head is attached to a 12.7 cm cable with a 19-pin circular connector which inserts into the front of the camera housing. The camera head interfaces with an ocular to transmit the image obtained by the SpyGlass Direct Visualisation Probe.

### Ocular

The ocular is a mechanical and ocular coupler that connects the SpyGlass Direct Visualisation Probe to the camera head. The ocular provides a focusing mechanism to sharpen the image on the video monitor.



**Note:** Monitor and pump (pictured here and on front of this brochure) are not currently available from Boston Scientific, but are recommended for use with the SpyGlass capital.\*

# Visualisation System

## COMPONENTS

### Isolation Transformer

Boston Scientific 1000 VA Medical Grade Isolation Transformer

Inputs	Outputs
120/240 VAC – 50/60Hz	120 or 240 VAC (voltage selector switch)
Input via an IEC 320 Power entry module	1000VA Maximum
On/off switch	9 Receptacles (IEC 320)

The transformer uses a 250V fuse and has an internal thermal resettable fuse.

### Power Cable Pack

The Power Cable Pack contains the following power cords:

Cord Length	Quantity	Connects to
0.5 m	2	Monitor, Irrigation pump (not supplied by Boston Scientific)
1.0 m	1	Spare (extra cord)
1.5 m	2	Camera, Lightsource

### SpyGlass Probe Storage Trays

The probe storage trays come in small and large sizes. They are designed to store and protect the SpyGlass Direct Visualisation Probe when not in use. The storage trays may also be used during high level disinfection of the SpyGlass Probe.\*

All of the components listed above are CE-marked.  
All of the components listed above have passed the required international safety standards.  
Applicable testing certification data on file, Boston Scientific Corporation.

\* Refer to the Directions for Use for disinfection

### SPYGLASS SYSTEM CAPITAL COMPONENTS

#### ORDERING INFORMATION

Part Number	Component	Dimensions in cm	Weight
M00546160	Components Cart <sup>1</sup>	49.5 W x 122.6 H x 53.3 D	68kg
M00546190	Lightsource	32 W x 14.2 H x 24.6 D	5.89kg
M00546110	Camera 240V (PAL) <sup>2</sup>	32 W x 10.2 H x 35.6 D	4.53kg
M00546070	3-Joint Arm with Clamp	80 cm long (extended)	0.73kg
M00546040	Ocular		<0.226kg
M00546210	Light Cable	12.7 cm long	<0.453kg
M00546240	Isolation Transformer (240 V)	30.5 W x 11.4 H x 21.8 D	10.432kg
M00546250	Power Cable Pack	Cables included: 2 – 0.5 meter 1 – 1 meter 2 – 1.5 meter	n/a
M00546060	Large Probe Storage Tray <sup>3</sup>	27.9 W x 5.1 H x 20.3 D	1.134kg
M00546050	Small Probe Storage Tray	17.8 W x 5.1 H x 14 D	0.589kg
M00546180	Components Assembly Manual		<0.453kg

**Note:** SpyGlass System, when completely assembled, has a space footprint of 49.5 cm W x 53.3 cm D. Total weight of the assembled system is 97.068kg.

**Note:** The ERBE Irrigation Pump (recommended for use with the SpyGlass Direct Visualisation System\*) is sold separately and distributed by your local ERBE distributor.

**Note:** The NDS Surgical Imaging EndoVue 48.3 cm (19") Medical Grade Monitor (recommended for use with the SpyGlass Direct Visualisation System\*) is sold separately and distributed by NDS Surgical Imaging.

\* Data on file Boston Scientific

<sup>1</sup> Cart includes a 3-joint arm with connector for ocular, but no table clamp

<sup>2</sup> Camera System includes camera controller (box), camera head, and video cables for connection to monitor. PAL version does not contain a power cord.

<sup>3</sup> Large Storage Trays are recommended unless the customer reprocesses in a machine into which the large storage trays will not fit. In this case, order two small storage trays, #M00546050.

# SpyScope™

Access and Delivery Catheter

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# SpyScope™

## Access and Delivery Catheter

The SpyScope Catheter is a single-use, single-operator controlled 10F (3.3 mm) device designed to provide a pathway into the biliary anatomy for diagnostic and therapeutic devices. It is comprised of two main components: a flexible delivery catheter with a handle designed to provide catheter tip orientation using dial controls. The catheter has four open lumens: one optic channel, one working device channel and two irrigation channels. The SpyScope Catheter attaches to a standard duodenoscope with a 4.2 mm working channel which allows a single physician to manage both scopes.

The tip of the SpyScope Catheter has four-way deflection, engineered to enhance directional control and permit more precise navigation within the biliary anatomy. The SpyGlass™ Direct Visualisation Probe, when loaded into the dedicated optic port, is designed to achieve complete circumferential visualisation. Circumferential visualisation may expand options for visual diagnosis and targeted tissue acquisition, potentially leading to accelerated diagnosis and altered patient treatment.\*

### SpyScope Catheter Specifications:

- Dedicated 1.2 mm accessory channel for multiple biopsy specimen retrieval with the SpyBite™ Biopsy Forceps
- 1mm optic channel for SpyGlass Direct Visualisation Probe facilitating illumination and endoscopic visualisation
- Independent irrigation channel for fluid aspiration, and to permit removal of debris that clears the field of vision of the SpyGlass Probe.
- 10F (3.3 mm) diameter catheter
- Catheter length = 230 cm



**Optic Port**



**Device Delivery Port**



**Irrigation Port**

## ORDERING INFORMATION

Order Code	Description
M00546230	SpyScope Access and Delivery Catheter

Recommended Guidewire: 0.035", 450 cm Jagwire™ Guidewire or 450 cm Hydra Jagwire™ Guidewire

\* "SpyGlass single operator peroral cholangiopancreatography system for the diagnosis and therapy of bile duct disorders: a clinical feasibility study"  
Yang Chen, MD, Douglas Pleskov, MD. Accepted for publication, GIE, May 2007

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# SpyGlass™

Direct Visualisation Probe

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# SpyGlass™

## Direct Visualisation Probe



**Probe Connector**



**Probe Tip**

The SpyGlass Direct Visualisation Probe is a fibre optic device designed to acquire and transmit endoscopic images, as well as conduct light to illuminate the biliary anatomy. The SpyGlass Probe contains a 6000 pixel image bundle, surrounded by approximately 225 light transmission fibres, which provide a field of light. The image bundle and light fibres are covered by an outer sheath which is engineered for flexibility and pushability. There is a lens connected to the image bundle at the distal tip. The lens captures images across a 70° field of view. The probe connects to an ocular and a light cable via the aluminum body at the proximal end.

The SpyGlass Ocular provides the mechanical and optical interface between the probe and video camera head. The light cable transmits light to the SpyGlass Probe from the light source.

The SpyGlass Direct Visualisation Probe enters the biliary anatomy through the SpyScope™ Access and Delivery Catheter. After the procedure, the SpyGlass Probe may be high-level disinfected for reuse.\*

The probe should be stored and protected in the small or large SpyGlass Storage Trays provided.

## ORDERING INFORMATION

Order Code	Description	Working Length	Field of View	Maximum Insertion Portion	Max. Diameter	Min. Req. Working Channel
M005 <b>46030</b>	SpyGlass Direct Visualisation Probe	231 cm	70°	0.81 cm	0.9 mm	1 mm
M005 <b>46040</b>	Ocular	—	—	—	—	—
M005 <b>46050</b>	Probe Small Storage Tray	—	—	—	—	—
M005 <b>46060</b>	Probe Large Storage Tray	—	—	—	—	—
M005 <b>46210</b>	Fibreoptic Light Cable	—	—	—	—	—

\* Please refer to the SpyGlass Direct Visualisation Probe Directions for Use.

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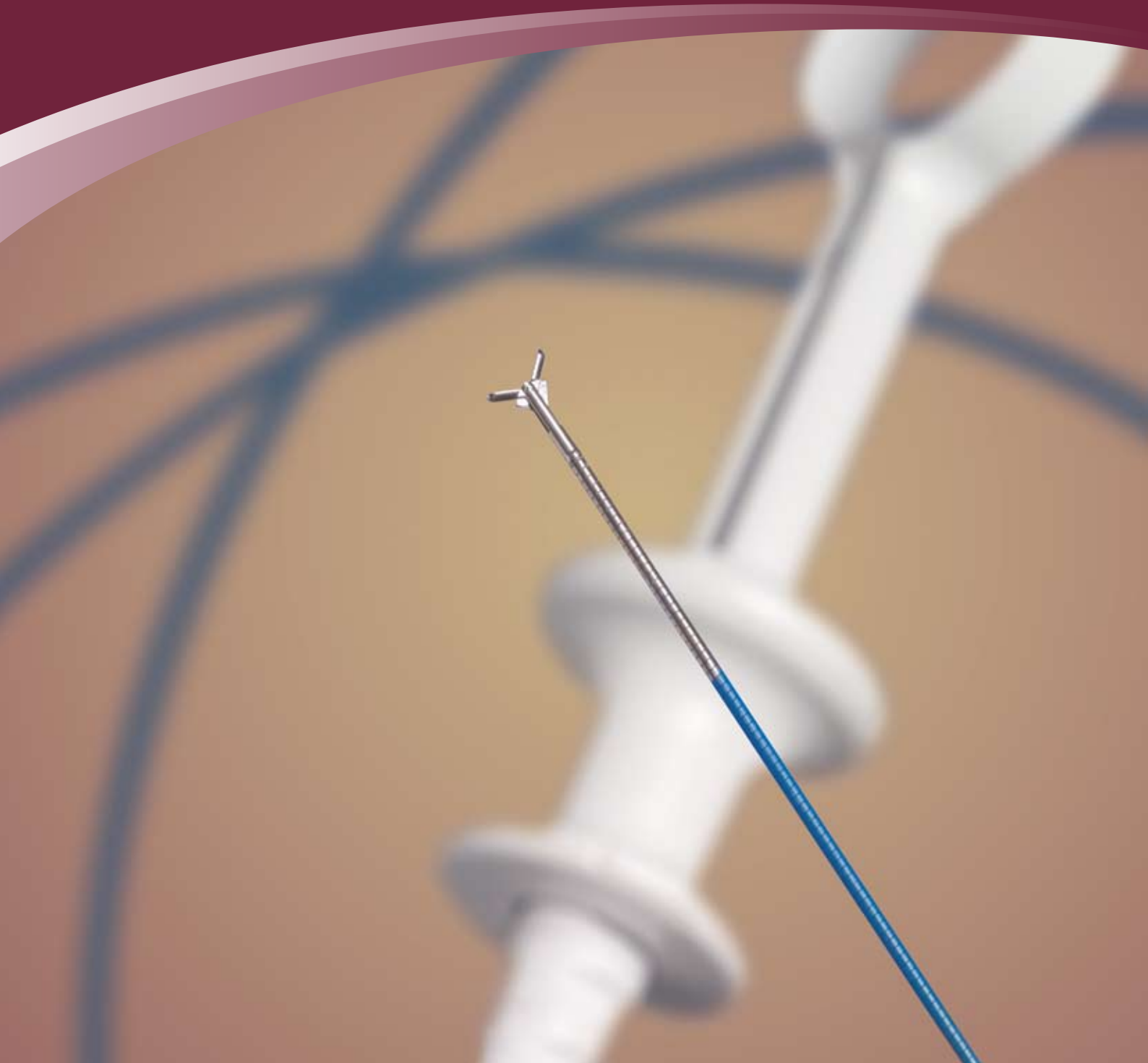
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**SpyBite™**

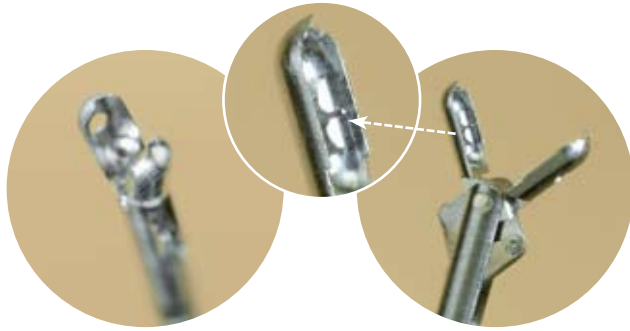
Biopsy Forceps

**Boston  
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# SpyBite™

## Biopsy Forceps



Using the SpyBite Forceps, site-specific biopsy specimens can be retrieved for examination from the common bile duct under direct visualisation, potentially accelerating diagnosis and reducing the need for repeat ERCP and other diagnostic procedures.

The SpyBite Biopsy Forceps are delivered into the biliary anatomy through an independent device port in the SpyScope™ Access and Delivery Catheter. The SpyBite Biopsy Forceps are designed with a central spike in the specimen cup to aid in securing small tissue samples.

## ORDERING INFORMATION

Order Code	Description	Cable Diameter	Jaw Outer Diameter	Jaw Opening	Working Length	Required Endoscope Working Channel
M005 <b>46270</b>	SpyBite Biopsy Forceps	0.99 mm (0.039")	1.0 mm	4.1 mm, 55°	286 cm	1.2 mm

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