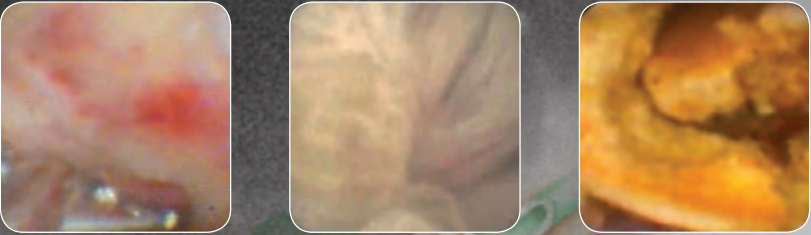


SpyGlass™
Direct Visualization System



A difference you can see.™

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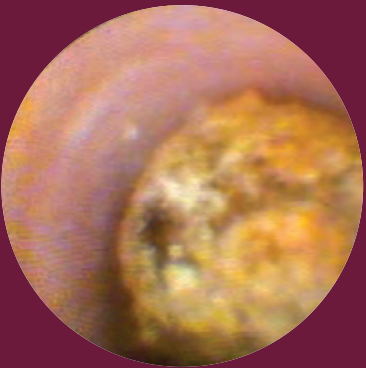
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SPYGLASS™ INTRADUCTAL IMAGES



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



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

- Provide endoscopic, site specific examination for visually guided tissue sampling and stone management
- 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 maneuverability*, allowing additional endoscopy suite staff to focus on patient care



*Data on file Boston Scientific Corporation
Illustrations and photos for information purposes - not indicative of actual shape, size or clinical outcome.

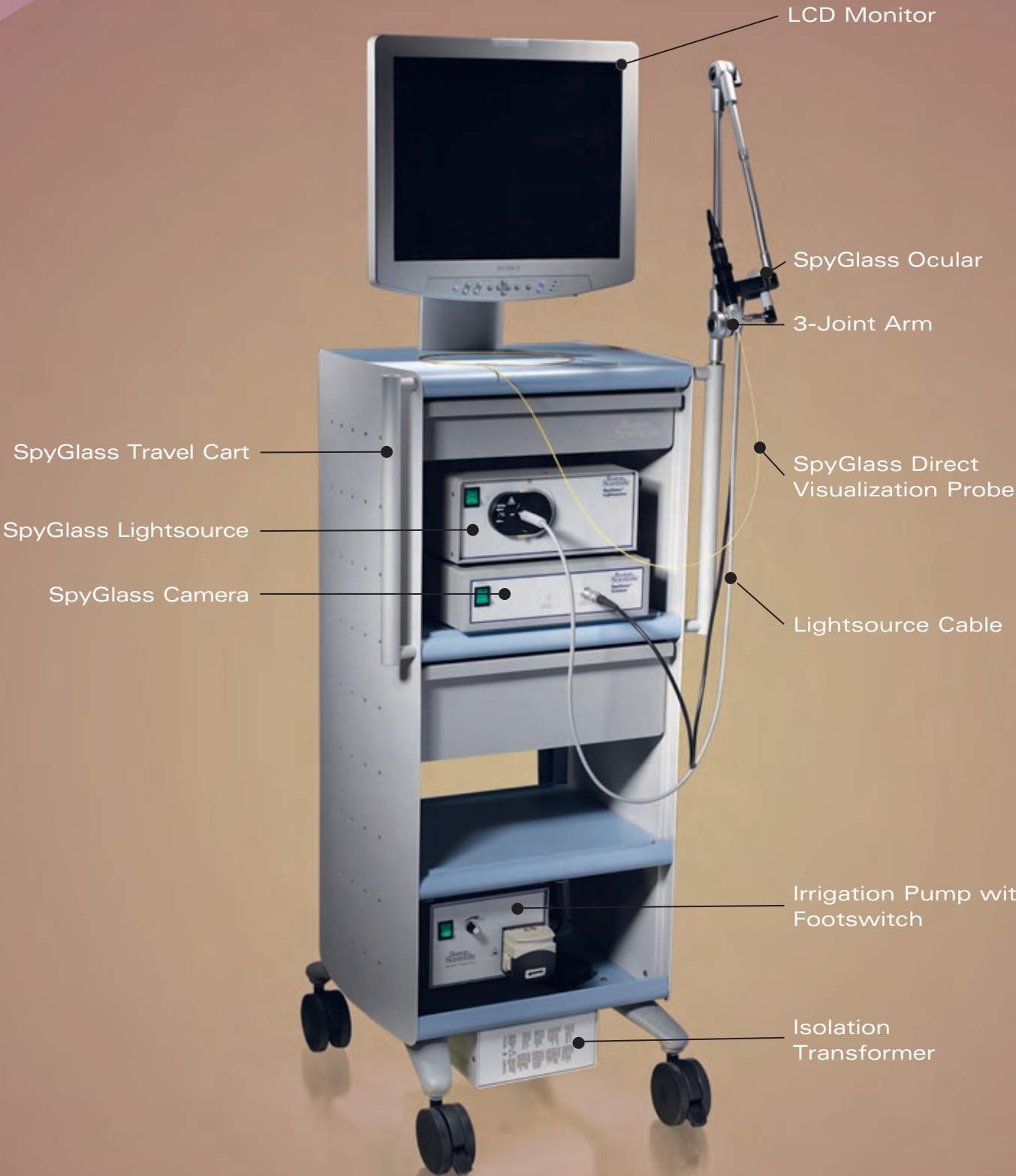
ORDERING INFORMATION

Part Number	Component	Dimensions in	Dimensions cm	Weight lbs	Weight kg
M005 46160	Travel Cart¹	19.5 W x 48.25 H x 21 D	49.5 W x 122.6 H x53.3 D	150	68
M005 46120	Video Monitor	17.5 W x 15.8 H x 4.75 D	44.45 W x 40.13 H x 12.07 D	20	9.06
M005 46190	Lightsource	12.6 W x 5.6 H x 9.7 D	32 W x 14.2 H x 24.6 D	13	5.89
M005 46110	Camera² 240V (PAL)	12.6 W x 4 H x 14 D	32 W x 10.2 H x 35.6 D	10	4.53
M005 46140	Irrigation Pump with Footswitch	8 W x 5.5 H x 6.5 D	20.3 W x 14 H x 16.5 D	5	2.26
M005 46070	3-Joint Arm with Clamp³	31.5 long (extended)	80 long (extended)	1.61	0.73
M005 46040	Ocular			<0.5	<0.226
M005 46210	Light Cable	5 long	12.7 long	<1	<0.453
M005 46240	Isolation Transformer (240V)	12 W x 4.5 H x 8.6 D	30.5 W x 11.4 H x 21.8 D	23	10.432
M005 46250	Power Cable Pack	Cables included:	2 – 0.5meter 1 – 1 meter 2 – 1.5meter	n/a	n/a
M005 46060	Large Probe Storage Tray⁴	11 W x 2 H x 8 D	27.9 W x 5.1 H x 20.3 D	2.5	1.134
M005 46050	Small Probe Storage Tray⁴	7 W x 2 H x 5.5 D	17.8 W x 5.1 H x 14 D	1.3	0.589
M005 46180	Components Assembly Manual			<1	<0.453

Note: SpyGlass System, when completely assembled with monitor, has a space footprint of 28in W x 70in H x 26in D (71.1cm x 177.8cm x 66cm). Total weight of the assembled system is 214lbs (97.01 kg).

¹ Cart includes a 3-joint arm with connector for ocular, but no table clamp
² Camera System includes camera controller (box), camera head, and video cables for connection to monitor. PAL version does not contain a power cord.
³ 3-Joint Arm (without clamp) is included with the Travel Cart (M005**46160**). The 3-Joint Arm with Clamp (M005**46070**) is useful if the account does not want to purchase the Travel Cart as it allows the account to mount the arm to another cart or table.
⁴ Large Storage Trays are recommended unless the customer reprocesses in an Olympus® Medivator Machine, into which the large storage trays will not fit. In this case, order two small storage trays, #M005**46050**.

* Olympus is a trademark of Olympus Corporation.
Medivator is a trademark of Minntech Corporation.



SpyGlass™ Direct Visualization System

Travel Cart and Three joint Arm

The travel cart has two storage drawers and two shelves for holding dividual components. The cart also has a mounting bracket for the video monitor and four casters for mobility. The three 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 three joint arm for secure attachment of the ocular.

Camera and Camera Head

The camera is a hospital grade medical device with a 6.4 mm (¼in) CCD color image sensor. The camera is equipped with Automatic White Balance (AWB) which is activated by momentarily depressing the AWB button. The camera can output three types of video signals:

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

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 (5in) 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 Visualization Probe.

Lightsource and Light Cable

The lightsource is a hospital grade medical device with a 300Watt xenon lamp. A digital meter records and displays the elapsed time (in hourly increments) the lamp has been used. 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).

Ocular

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

Video Monitor

The video monitor is a hospital grade LCD that is designed to attach to the Travel Cart. The video monitor combines SXGA high-resolution (1280 x 1024) panel and high brightness/ultra-wide field of view technology, enabling you to use the monitor under various lighting conditions.



Irrigation Pump and Footswitch

The irrigation pump and footswitch are hospital grade devices that provide irrigation to the SpyScope™ Access and Delivery Catheter and are designed to irrigate the duct, maintain clear visualization and clear the duct of debris. The flow rate is controlled by adjusting the irrigation pump and pressing the footswitch provides continuous flow. The irrigation pump is designed to work with the SpyGlass Irrigation Tubing.

Pump Specifications	
Weight	5.0 lbs (2.27 kg)
Dimensions W x H x D	8in x 5½in x 6½in (203 x 140 x 165 mm)
Power	100-240 V~, 50/60Hz, 25VA
Flow Rate	0-375ml/min +/- 20 % using SpyGlass Irrigation Tube Set M005 46451 (without SpyScope Access and Delivery Catheter)

Isolation Transformer

The isolation transformer is designed to work with the SpyGlass Power Cable Pack and offers added safety when using electronics or electromedical devices. The transformer generates low EMI (Electro Magnetic terference), typically less than 100µA and runs quite cool, also at a rated full load. The transformer uses a 250V fuse and has an internal thermal resettable fuse.

Inputs	Outputs
120/240VAC – 50/60Hz	120 or 240 VAC (voltage selector switch)
Input via an IEC 320 Power entry module	100VA Maximum
On/off switch	9 Receptacles (IEC 320)

Power Cable Pack

The Power Cable Pack contains the following power cords:

Cord Length	Quantity	Connects to
0.5m	2	Monitor, Irrigation pump
1.0m	1	Spare (extra cord)
1.5m	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 Visualization Probe when not in use. The storage trays may also be used during high level disinfection of the SpyGlass Probe.*

Large storage trays are recommended unless the customer reprocesses in an Olympus® Medivator® Medicine, into which the large storage trays will not fit. In this case, order two small storage trays, #M005**46050**.

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 (3.3mm) device designed to provide a pathway into the pancreato-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 4.2mm 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 pancreato-biliary anatomy.* The SpyGlass™ Direct Visualization Probe, when loaded into the dedicated optic port, is designed to achieve complete circumferential visualization. Circumferential visualization may expand options for visual diagnosis and targeted tissue acquisition, potentially leading to accelerated diagnosis and altered patient treatment.**

SpyScope Catheter Specifications:

- Dedicated 1.2mm accessory channel for biopsy specimen retrieval with the SpyBite™ Biopsy Forceps or stone management w/EHL or laser fiber***
- 1mm optic channel for SpyGlass Direct Visualization Probe facilitating illumination and endoscopic visualization
- Independent irrigation channel for fluid aspiration, and to permit removal of debris that clears the field of vision of the SpyGlass Probe
- 10F (3.3mm) diameter catheter
- Catheter length = 230cm



Distal Tip



Optic Port



Device Delivery Port



Irrigation Port

ORDERING INFORMATION

Order Code	Description
M00546230	SpyScope Access and Delivery Catheter

Recommended Guidewire: 0.89mm (0.035in), 450cm Jagwire™ Guidewire or 450cm Hydra Jagwire™ Guidewire

* Data on file Boston Scientific Corporation

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

*** The SpyGlass System has also been shown to be compatible with the Northgate® 1.9Fr Biliary Probe (9-195-25) and the Northgate Autolith® Intracorporeal Electrohydraulic Lithotripsy iEHL Generator (9-201-00) for EHL applications. The SpyGlass System has also been shown to be compatible using the Lumenis® SlimLine™ 365 micron Laser probe (M0068408420) and the Lumenis® VersaPulse PowerSuite 20Watt Holmium Laser Generator (M0068408220). The testing followed the laser probe placement instructions.

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SpyGlass™

Direct Visualization Probe

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SpyGlass™

Direct Visualization Probe



Probe Tip



Probe Connector



Optic Port

The SpyGlass Direct Visualization Probe is a fiber optic device designed to acquire and transmit endoscopic images, as well as conduct light to illuminate the pancreatobiliary anatomy. The SpyGlass Probe contains a 6000 pixel image bundle, surrounded by approximately 225 light transmission fibers, which provide a field of light. The image bundle and light fibers 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 that 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 Visualization Probe enters the pancreatobiliary anatomy through the SpyScope™ Access and Delivery Catheter. After the procedure, the SpyGlass Probe may be high-level disinfected for reuse.¹

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

ORDERING INFORMATION

Order Code	Description	Working Length	Field of View	Maximum Insertion Portion	Max. Diameter	Min. Req. Working Channel
M005 46030	SpyGlass Direct Visualization Probe	231cm	70°	0.81mm	0.9mm	1mm
M005 46040	Ocular	—	—	—	—	—
M005 46050	Probe Small Storage Tray ²	—	—	—	—	—
M005 46060	Probe Large Storage Tray ²	—	—	—	—	—
M005 46210	Light Cable	—	—	—	—	—

¹ Please refer to the SpyGlass Direct Visualization Probe Directions for Use.

² Large Storage Trays are recommended unless the customer reprocesses in an Olympus® Medivator® Machine, into which the large storage trays will not fit. In this case, order two small storage trays, #M005**46050**.

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SpyBite™

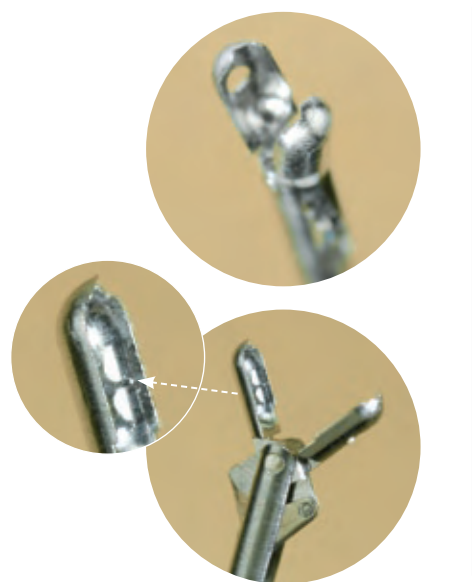
Biopsy Forceps

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SpyBite™

Biopsy Forceps



Using the SpyBite Biopsy Forceps, site-specific biopsy specimens can be retrieved for examination from the common bile duct under direct visualization, potentially accelerating diagnosis and reducing the need for repeat ERCP and other diagnostic procedures. The SpyBite Biopsy Forceps are delivered into the pancreatobiliary 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 46270	SpyBite Biopsy Forceps	0.99 mm (0.039 in)	1.0 mm	4.1 mm, 55°	286 cm	1.2 mm

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