

SpyGlass™

Direct Visualisation System and Capital Components

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User Reference Guide

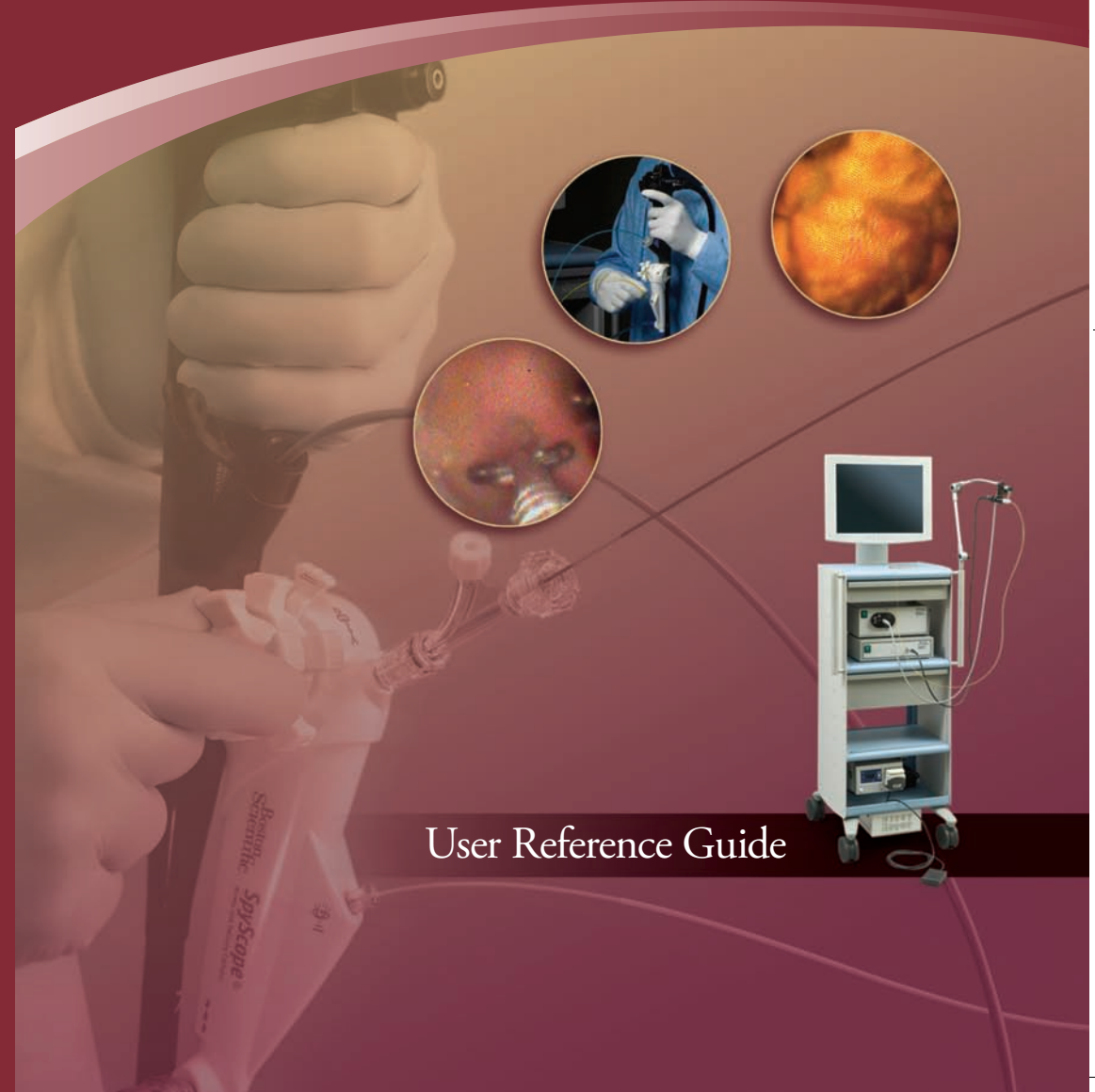


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This overview is provided for illustrative purposes only and is intended only as a brief summary of how the procedural steps for using the SpyGlass™ Direct Visualisation System are generally performed. Please refer to the Directions For Use for complete instructions.

1 SpyGlass™ System Capital Components and Consumable Devices

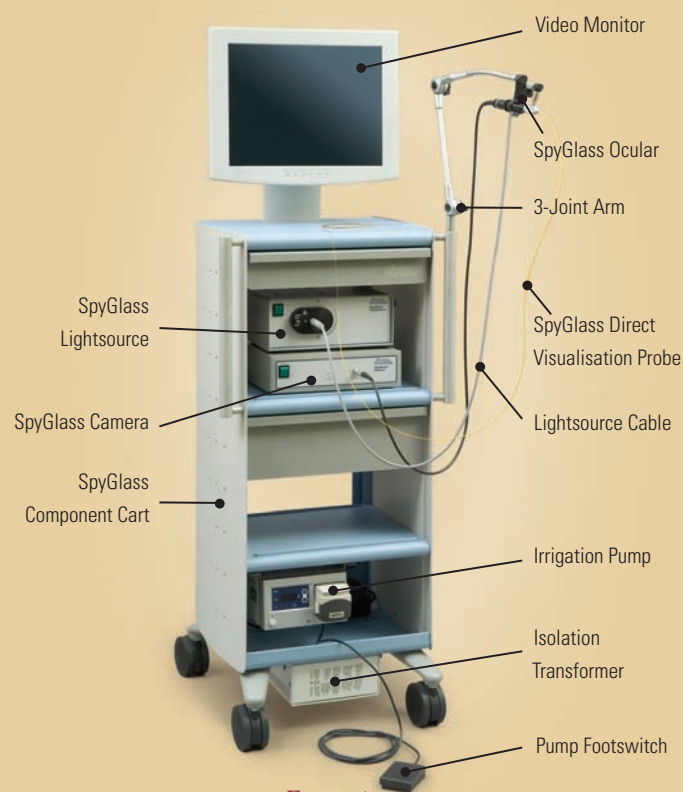


Figure 1



Figure 2



Figure 3

SpyGlass™ System Capital Components and Consumable Devices (Figure 1)

The capital system contains several components that will require assembly:

- SpyGlass Camera – Auto shutter camera with 6.4 mm CCD chip
- SpyGlass Ocular – optical coupler that interfaces with the SpyGlass Probe and the video camera head
- SpyGlass Lightsource – 300 watt, high intensity white light
- SpyGlass Travel Cart – includes 3-joint arm for extension
- Isolation Transformer
- Irrigation Pump with Footswitch

Consumable Devices

SpyGlass Fibre Optic Probe (Figure 2)

- 6000 pixel fibre optic probe
- 70 degree field view
- 0.33 in (8.4 mm) outside diameter
- 365 cm long
- Fibre optic bundle surrounded by light fibres
- Multiple use device that is reprocessed after each use

SpyScope™ 10 F (3.3 mm) Access & Delivery Catheter (Figure 3)

- Multi-lumen catheter including:
 - One 1.2 mm accessory channel
 - Two independent irrigation channels
 - One 1.0 mm optical channel
 - Four steering wires embedded in length of the catheter

SpyBite™ Biopsy Forceps

- Minimum working channel of 1.2 mm required
- Jaw outside diameter: 1 mm closed, 4 mm open
- 286 cm working length
- Single-use device

2 Verifying Power



Figure 4

To prepare for a procedure, check that all of the capital components are plugged into the isolation transformer mounted below the bottom shelf of the cart. Verify that the power inlet cord attached to the isolation transformer is plugged into a wall outlet.

- Turn on the power switch on the isolation transformer.
- Turn the power on for the monitor, lightsource, camera and irrigation pump.

(Figure 4)

- Verify that an image appears on the video monitor. The monitor will have a dull, indistinct white-gray image.
- Do not shine light directly into the camera as this may damage the imaging sensor.

NOTE: A clear image will not be seen until the SpyGlass™ Probe is connected.

3 Pre-Procedure Set-Up

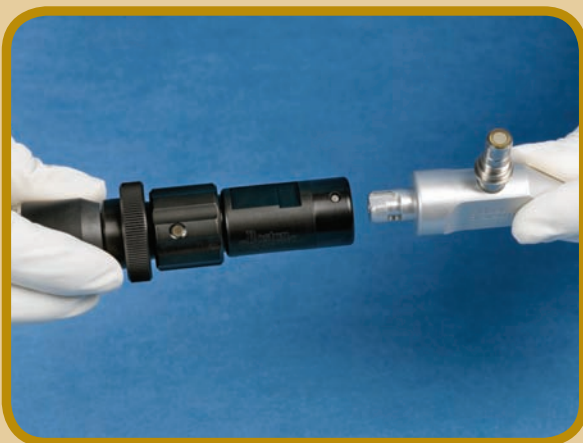


Figure 5

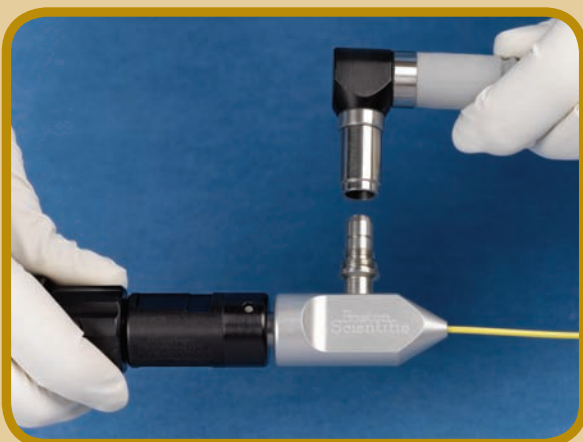


Figure 6

The SpyGlass™ System procedure is an extension of a typical ERCP, so initial steps are the same as or similar to an ERCP. Pre-procedure device set-up is required. A review of select pre-procedure set-up and typical procedural steps are listed below. For complete instructions, please refer to the individual component Directions for Use.

Pre-Procedure Set-Up

- Set up video camera and ocular
 - Thread ocular into front of video camera head
 - If 3-joint arm is used, attach ocular to holder
 - Line up the groove in the ocular with the tongue on the ocular holder

NOTE: The “tongue” on the ocular holder is a slightly raised area on the top of the C-shaped slot.

- Push the ocular into the C-shaped receptacle on the ocular holder until it contacts the far wall of the holder
- Rotate the ocular back and forth until an audible click can be heard, which verifies that the ocular is locked in place
- Remove probe and verify that it has been high-level disinfected or sterilised
 - Inspect probe for rough surfaces, sharp edges or protrusions
 - Do not use if:
 - Outer jacket is torn or abraded through
 - Probe is kinked and/or permanently bent
 - Attach probe to ocular (**Figure 5**)
- Attach light cable to adapter light post on the probe (**Figure 6**)
- Turn on video camera, monitor and lightsource (if they are not already on)

4 Image Quality Test



Figure 7

Before a procedure, the following steps should be taken to test the image quality of the capital equipment and the SpyGlass™ Probe image:

- Turn the lightsource to a mid-level power

NOTE: Lightsource cable should be attached to SpyGlass Probe at this point.

- Verify a proper image using the SpyGlass Probe test target. Refer to the white index card included in the SpyGlass Probe packaging.
- Adjust focus ring so image becomes clear within 1 cm of SpyGlass Probe test target. **(Figure 7)**

NOTE: Refocusing should not be required once the procedure begins.

- Point the probe at a white object. Press the white balance button on the front of the camera control unit.

5 Preparing and Using the SpyScope™ Access and Delivery Catheter



Figure 8

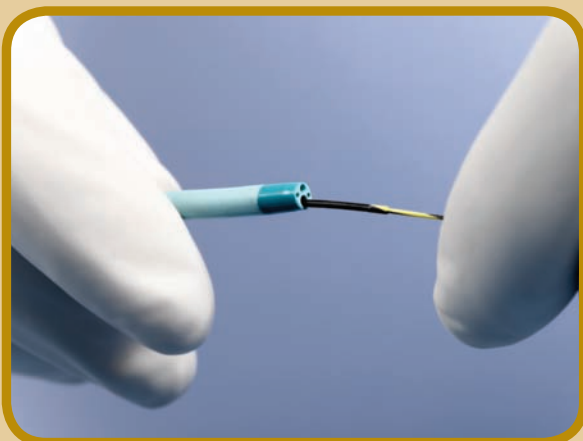


Figure 9

- Attach the SpyScope Catheter to the duodenoscope by securing the plastic strap onto the handle of the duodenoscope.
- Through the optic port on the handle of the SpyScope Access and Delivery Catheter, load the SpyGlass™ Probe, and advance using short strokes. **(Figure 8)** You'll be able to see the lighted, fibre optic probe going through the catheter.
- Advance the probe until it is flush with the end of the SpyScope Catheter. As you approach the distal end of the SpyScope Catheter, you will observe on the monitor that the visible image changes from a translucent appearance to teal/blue.
- Check to be sure there is still a good image on the monitor to verify the probe was not damaged during insertion into the SpyScope Catheter.

NOTE: To avoid damage to the probe, pull the probe a few millimeters back into the catheter during insertion of the catheter and probe into the duodenoscope.

- If a guidewire will be used in the procedure, backload a 450 cm wire into the working channel of the SpyScope Catheter before delivering the catheter and probe through the duodenoscope. **(Figure 9)**

NOTE: If a guidewire is not required for cannulation and the SpyBite™ Biopsy Forceps will be used, you may preload the SpyBite Biopsy Forceps prior to passing the SpyScope Catheter.

- Ensure the probe is pulled back into the catheter several millimeters to avoid damage to the probe.
- Using short strokes, insert the SpyScope Catheter and SpyGlass Probe into the working channel of the duodenoscope, over the elevator and into the Ampulla of Vater.

NOTE: Ensure the elevator of the duodenoscope is down as the SpyScope Catheter exits the duodenoscope.

- Adjust the position of the probe inside the SpyScope Catheter as required during the procedure.

6 Accessory Passage

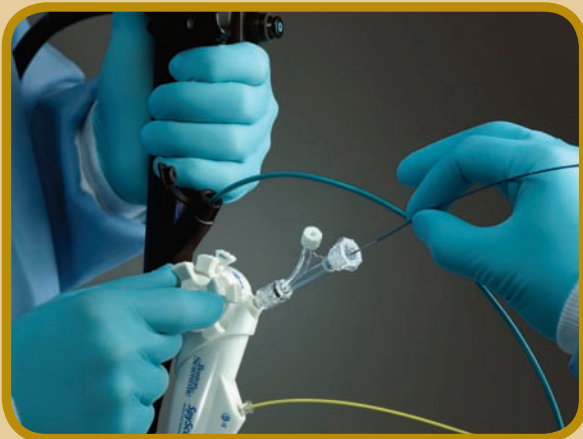


Figure 10

- If not already preloaded, insert the SpyBite™ Biopsy Forceps into the device port of the SpyScope™ Catheter. **(Figure 10)**
- Advance the SpyBite Biopsy Forceps using short strokes. Once the forceps exit the tip of the SpyScope Catheter, the forceps can be extended to obtain a tissue sample.
- Before advancing the SpyBite Biopsy Forceps through the SpyScope Catheter, apply light pressure on the handle to make sure the jaws remain closed.
- Ensure the elevator of the duodenoscope is down as the SpyScope Catheter exits the duodenoscope.

7 Probe and Ocular Care and Storage



Figure 11

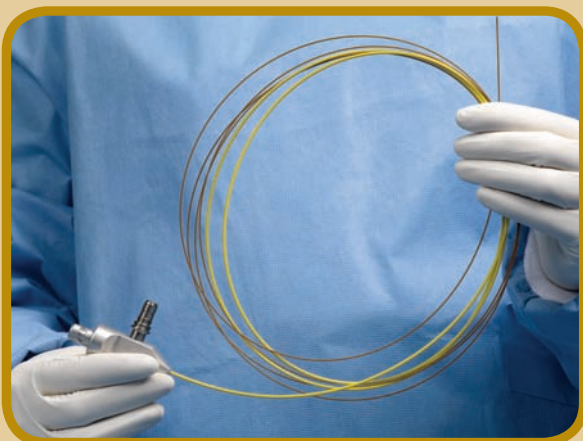


Figure 12

- When the procedure is complete, pull the SpyGlass™ Probe a few millimeters back into the SpyScope™ Catheter, detach the light cable from the probe by firmly holding the aluminum portion of the probe and detaching distal portion of the light cable.
 - Detach the SpyGlass Probe from the ocular by rotating the probe in a counter-clockwise direction, and then pulling the probe straight off the ocular.
 - Wipe the SpyGlass Probe distal and proximal lenses and ocular clean using a soft cloth or gauze. **(Figure 11)** Do not leave any residue on the window of the ocular. The ocular can be stored on the camera head or in the drawer of the SpyGlass Components Cart.
 - After scope is removed from the body, carefully remove the probe from the scope. Wipe with an enzymatic cleaner and then carefully wind the probe in the tray for cleaning.
- NOTE:** The SpyGlass Probe should be coiled and transported using two hands as shown in **Figure 12**.
- With proper handling and care, the SpyGlass Probe can be used for multiple uses. Before each use, the probe is reprocessed according to the recommended methods identified in the reprocessing section of the SpyGlass Probe Directions for Use.

NOTE: The probe contains no hazardous materials. When the probe no longer delivers a satisfactory image, dispose of the device in accordance with hospital, administrative and/or local government policy.

8 SpyGlass™ System Components Ordering Information

CAPITAL COMPONENTS

PART NUMBER	COMPONENT	DIMENSIONS in cm	WEIGHT
M00546160	Components Cart ¹	49.5 W x 122.6 H x 53.3 D	68 kg
M00546190	Lightsource	32 W x 14.2 H x 24.6 D	5.89 kg
M00546110	Camera 240V (PAL) ²	32 W x 10.2 H x 35.6 D	4.53 kg
M00546120	Video Monitor	48.3 cm (19")	n/a
M00546140	Irrigation Pump with Footswitch	20.3 W x 14 H x 16.5 D	2.26 kg
M00546070	3-Joint Arm with Clamp ¹	80 cm long (extended)	0.73 kg
M00546040	Ocular		<0.226 kg
M00546210	Light Cable	12.7 cm long	<0.453 kg
M00546240	Isolation Transformer (240 V)	30.5 W x 11.4 H x 21.8 D	10.432 kg
M00546250	Power Cable Pack	(Cables included): 2 – 0.5 meter 1 – 1 meter 2 – 1.5 meter	n/a
M00546060	Large Probe Storage Tray ³	27.9 W x 5.1 H x 20.3 D	1.134 kg
M00546050	Small Probe Storage Tray ³	17.8 W x 5.1 H x 14 D	0.589 kg

CONSUMABLE DEVICES

PART NUMBER	COMPONENT	WORKING LENGTH	MINIMUM WORKING CHANNEL
M00546270	SpyBite™ Biopsy Forceps	286 cm	1.2 mm
M00546030	SpyGlass Probe	231 cm	1 mm
M00546230	SpyScope™ Access & Delivery Catheter	230 cm	4.2 mm
M00546451	SpyGlass Irrigation Tube Set (Box 10)		

NOTE: SpyGlass System, when completely assembled, has an approximate space footprint of 49.5 cm W x 53.3 cm D.
Total weight of the assembled system is approximately 97.068 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 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.



9 Intended Use

CAPITAL COMPONENTS

SpyGlass™ Camera System

INDICATIONS FOR USE

The SpyGlass Camera System is for use during diagnostic and/or surgical procedures when endoscopic video assistance is required.

WARNING

Operators who are not trained and qualified to perform endoscopic procedures should not use this device.

Always exercise safety precautions when using electrical equipment to prevent operator and patient shock, fire hazard, or equipment damage. When implemented for therapeutic applications, a second equivalent camera should be available in case the primary camera stops working.

CONTRAINDICATIONS

None known.

SpyGlass Lightsource

INDICATIONS FOR USE

Boston Scientific SpyGlass Lightsource is used for surgical lighting and other applications.

WARNING

Operators who are not trained and qualified to perform endoscopic procedures should not use this device.

When implemented for therapeutic applications, a second equivalent lightsource should be available in case the primary lightsource stops working.

CONTRAINDICATIONS

None known.

Irrigation Pump and Footswitch

INDICATIONS FOR USE

To provide irrigation during endoscopic surgical procedures.

WARNING

Operators who are not trained and qualified to perform endoscopic procedures should not use this device.

CONTRAINDICATIONS

None known.

Isolation Transformer

INTENDED USE

The Isolation Transformer is intended for applications where medical devices require improved electrical isolation and/or reduced leakage current to comply with existing safety standards. With the Isolation Transformer connected between the device and the wall outlet where the device is installed, the leakage current and the electrical isolation of the installed device will be that of the Isolation Transformer.

SpyGlass Light Cable

INDICATIONS FOR USE

Boston Scientific Light Cable is for use with cystoscope, arthroscopes, pediatric endoscopes, and others.

WARNING

Operators who are not trained and qualified to perform endoscopic procedures should not use this device. When implemented for therapeutic applications, a second equivalent light cable should be available in case the primary light cable stops working.

CONTRAINDICATIONS

None known.

CONSUMABLE DEVICES

SpyScope™ Access and Delivery Catheter

INTENDED USE

The device is intended to guide the SpyGlass™ Direct Visualisation Probe or other Visualisation probe and various accessory devices into the biliary duct system during endoscopic biliary duct exploration procedures.

INDICATIONS FOR USE

The SpyScope Device is intended to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the biliary system including the hepatic ducts.

CONTRAINDICATIONS

Contraindications for this device are those specific to endoscopic biliary duct exploration and cannulation.

SpyGlass Direct Visualisation Probe and Ocular

INTENDED USE

The SpyGlass Probe and Ocular have been designed to examine the biliary system and associated ducts and organs.

INDICATIONS FOR USE

The SpyGlass Probe and Ocular are intended to provide direct visualisation for examination for diagnostic and therapeutic applications during endoscopic procedures in the biliary system including the hepatic ducts.

CONTRAINDICATIONS

Contraindications associated with the use of the SpyGlass Probe and Ocular include:

- Patients for whom endoscopic procedures are medically contraindicated.
- Patients for whom endoscopic retrograde cholangiopancreatography (ERCP) is medically contraindicated.
- Any use other than those specifically outlined under the Indications for Use.

SpyBite™ Biopsy Forceps

INTENDED USE

The SpyBite Biopsy Forceps are designed to collect tissue samples endoscopically for histologic examination. These instruments should not be used for any purpose other than the intended function.

INDICATIONS FOR USE

The SpyBite Biopsy Forceps are indicated for tissue acquisition in the pancreaticobiliary system.

CONTRAINDICATIONS

Contraindications for this device are those specific to endoscopic retrograde cholangiopancreatography (ERCP) procedures.

