

SpyScope™ DS and SpyScope DS II Access & Delivery Catheter

For Use with the SpyGlass™ DS Digital Controller

REFER TO THE DEVICE DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS ON DEVICE USE. RX ONLY.
CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Warning

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative. For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

NOTE: SpyScope DS Catheter (M00546600) is compatible with Controllers with software revisions 2.1 and 2.2. SpyScope DS II Catheter (M00546610) is compatible with Controllers with software revision 2.2 only.

Intended Use/Indications For Use

The SpyGlass DS and DS II Direct Visualization System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts. The SpyGlass DS and DS II Direct Visualization System comprises two components: the SpyScope DS Access and Delivery Catheter or SpyScope DS II Access and Delivery Catheter, and the SpyGlass DS Digital Controller.

The SpyScope DS Access and Delivery Catheter and SpyScope DS II Access and Delivery Catheter are intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

The SpyGlass DS Digital Controller is intended to provide illumination and receive, process, and output images from the SpyScope DS Access and Delivery Catheter or SpyScope DS II Access and Delivery Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.

Contraindications

Contraindications associated with the use of this device include:

- Patients for whom ERCP is medically contraindicated.
- Contraindications specific to endoscopic pancreatico-biliary duct exploration and cannulation.

Warnings

- Do not use the SpyScope DS Catheter in the presence of uncontained flammable fluids or gases such as detergents, anesthetics, nitrous oxide (NO), or oxygen. Doing so can result in fire and burns to the operator and patient.
- Do not use irrigation tubing without a single-use, one-way valve in place to prevent backflow. Doing so can result in contamination of the device and/or cause patient infection or cross-infection.
- The SpyScope™ DS Catheter is not intended to be used with RF cutting/coagulation devices.

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Precautions

- Only use the SpyScope DS Catheter in conjunction with the SpyGlass™ DS Digital Controller. Connection to other devices may cause device or property damage or operator injury.
- Excessive bending of the articulation portion of the SpyScope DS Catheter with the elevator of the duodenoscope can break or kink the articulation portion. Do not bend the articulation portion excessively with the duodenoscope elevator.
- The SpyScope DS Catheter should be used with caution in patients with previous gastric or bile duct surgery, or with ductal strictures. These conditions may prevent passage of the SpyScope DS Catheter.

Adverse Events

Possible complications include, but may not be limited to:

- Pancreatitis
- Hematoma
- Allergic reaction to contrast medium
- Perforation
- Septicemia/infection
- Mucous membrane damage
- Hemorrhage
- Cholangitis