



***Refer to the device directions for use for complete instructions on device use.***

**Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.**

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## ***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.

## ***Intended Use/ Indications For Use***

The SpyGlass Discover Digital System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts. The SpyGlass Discover Digital System comprises two components: the SpyGlass Discover Digital Catheter and the SpyGlass Discover Digital Controller.

The SpyGlass Discover Digital Catheter is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatobiliary system including the hepatic ducts.

The SpyGlass Discover Digital Controller is intended to provide illumination and receive, process, and output images from the SpyGlass Discover Digital 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:

- Contraindications specific to pancreatobiliary duct (including hepatic ducts) exploration and cannulation.



## Warnings

- Do not use the SpyGlass Discover Digital 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 perform therapy when an accessory is outside the field of view or force the distal end of the SpyGlass Discover Digital Catheter against the mucosa. Doing so can result in patient injury such as perforation, hemorrhage, or mucous membrane damage.
- 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.
- Do not look directly into the light emitted from the SpyGlass Discover Digital Catheter. Doing so can result in eye injury.
- The face of the cable remains hot for a period of time after disconnection from the controller. Do not touch the face of the cable connector immediately after removing it from the controller. Doing so can result in a skin burn.
- If using the Y-port adapter, open the Y-port adapter before back-loading over a guidewire to ensure that guidewire is not pushed further into the anatomy resulting in perforation.
- The SpyGlass™ Discover Digital Catheter is not intended to be used with RF cutting/ coagulation devices.
- WARNING: No modification of this equipment is allowed.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

## Adverse Events

Possible complications include, but may not be limited to:

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