SpyGlass™ Discover Digital Catheter

Rx Statement

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.*

Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

REUSE WARNING
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.

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 pancreatico-biliary 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 specific to pancreatico-biliary 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.
- 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.

PRECAUTIONS

- Note: SpyGlass Discover Digital Catheter is compatible with SpyGlass Discover Digital Controller only.
- Note: The working channel of the SpyGlass Discover Digital Catheter should be flushed with saline after the use of contrast media. If the channel is not flushed, accessory devices may not pass through the channel and tip articulation may be reduced.
- Only use the SpyGlass Discover Digital Catheter in conjunction with the SpyGlass Discover Digital Controller. Connection to other devices may cause device or property damage or operator injury.
- Excessive bending of the articulation portion of the SpyGlass Discover Digital Catheter can break or kink the articulation portion. Do not bend the articulation portion excessively.
- Note: If breakage or kinking of the SpyGlass Discover Digital Catheter is confirmed under X-ray, stop using the SpyGlass Discover Digital Catheter immediately.
- Activating a laser or electrohydraulic lithotripsy (EHL) generator within close proximity of the SpyGlass Discover Digital Catheter distal end can damage the distal end. Consult the instructions for use of the laser or EHL manufacturer for the appropriate distance between the laser fiber or EHL probe and the SpyGlass Discover Digital Catheter distal end. At a minimum, ensure the laser fiber or EHL probe is extended at least 2 mm (0.08 in.) beyond the distal end before actuating the laser or EHL.
- Disconnecting the catheter cable from the controller before removing the insertion portion will result in a loss of visualization. Remove the SpyGlass Discover Digital Catheter from the laparoscopic port before unplugging the cable.
- Damaging the face of the catheter cable connector can result in no visualization or an unexpected loss of visualization. Handle the cable with care and inspect the face of the catheter cable connector for damage before use.
- Using a cardiac defibrillator while a SpyGlass Discover Digital Catheter remains in a patient can damage the controller. Remove the SpyGlass Discover Digital Catheter before using the defibrillator.
- The SpyGlass Discover Digital 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 SpyGlass Discover Digital Catheter.
- Do not insert a wet connector cable plug into the SpyGlass Discover Digital Controller as poor video performance or damage to the system may result.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SpyGlass System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment

POTENTIAL ADVERSE EVENTS

Possible complications include, but may not be limited to:

- Allergic reaction
- Cholangitis
- Embolism
- Hematoma
- Hemorrhage
- Infection/Septicemia
- Inflammation
- Mucous membrane damage/ Tissue Damage
- Pain/Discomfort
- Pancreatitis
- Perforation