



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.

Intended Use/ Indications For Use

The SpyGlass Discover Digital System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts. The SpyGlass Discover Digital System comprises of 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 associated with the use of this device include:

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

Warnings

- Read this user manual, the SpyGlass Discover Digital Catheter directions for use, and the monitor user manual before using the controller. Failure to follow any instructions or failure to heed any warnings or precautions may result in harm or injury to patient.
- Do not use the controller in the presence of flammable fluids and gases such as alcohol or oxygen. Doing so can result in fire and burns to the operator and patient.
- Do not perform diagnostic or therapeutic procedures without a clear and adequate video display. Doing so can result in adverse events.
- If the controller is connected to an improperly grounded power supply, electrical leakage can result in electrical shock to the user. To avoid risk of electrical shock, this equipment must only be connected to a supply mains with protective earth.

Precautions

- If you block the controller's ventilation outlet, the controller can overheat, resulting in a thermal shutdown or equipment damage. Leave at least 12.7 mm (0.5 in) between the controller back panel and other objects and 12.7 mm (0.5 in) of space between the side panels and other objects.
- Spilling liquids on the controller can damage it or cause it to shut down. Do not place liquids above or near the controller.

Adverse Events

See directions for use for SpyGlass Discover Digital Catheter for adverse event information.