



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.

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.

Contraindications

None Known.

Warning

- Appropriate placement of the catheter should be confirmed before it is introduced.
- Care should be taken when introducing the catheter and the guidewire; use of excessive force may result in damage or perforation within the pancreaticobiliary system.

Precaution

Before using, inspect the pouch for any breach of the package to ensure a sterile product.

Adverse Events

Possible complications include, but may not be limited to:

- Pancreatitis
- Perforation
- Hemorrhage
- Hematoma
- Septicemia/infection
- Cholangitis
- Mucous membrane damage

Intended Use/ Indications For Use

The SpyGlass Discover Imager II IOC Catheter is indicated for use in facilitating access to the cystic duct and may be used in conjunction with a guidewire or for the infusion of radiopaque contrast material.